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PESTICIDE FOOD SAFETY ACT OF 1988

FOR RECORD ONLY:

HEARINGS

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

SECOND SESSION

ON

H.R. 4937

JULY 28 AND SEPTEMBER 7, 1988

Serial No. 100-99



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(III)

PESTICIDE FOOD SAFETY ACT OF 1988

THURSDAY, JULY 28, 1988

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:26 a.m., in room 1302, Longworth House Office Building, Hon. George E. Brown, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Staggers, Espy, Roberts, and Grandy.

Staff present: Francie Monaghan, clerk; William A. Stiles, Jr., James A. Davis, and John J. Aguirre.

OPENING STATEMENT OF HON. GEORGE E. BROWN, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. BROWN. The subcommittee will come to order, and I would note that it is 3 minutes before the announced time for our beginning. Unfortunately, due to a confluence of circumstances over which the subcommittee has no control, we are forced to make some changes in the hearing planned for this particular subject.

And what we intend to do is as follows. We will hear Dr. John Moore and his testimony and spend as much time as is necessary elucidating his wise counsel, and commenting on it. And then we will ask, with great regret, the remaining witnesses if they can return at a later date which we have tentatively set for a week from today, Thursday, August 4, at 2 p.m., in room 1300.

The reasons for this are that practically all of the members of the committee will be involved in the discussion of the drought bill which will be on the floor at 10 o'clock this morning or shortly thereafter. And that includes our distinguished ranking minority member who will be playing a leading role in that, and it may even include the chairman, who will be playing a minor role in that.

And we feel that it would be unfair to the witnesses to try and give them the consideration that they are entitled to in view of the conflict that this presents to us. So all we can do is apologize profusely and hope that they will be able to return a week from today so that we may continue with this extremely important subject and develop a position on it as quickly as possible.

Now I regret very much that this is necessary, but we will have to proceed on that basis. With that understanding, I invite Dr. Moore to come to the table and present his testimony. I might note that this is probably the last time that we will ever see Dr. Moore

in his role as Assistant Administrator for Pesticides and Toxic Substances——

Mr. ROBERTS. I am glad you added that last part, Mr. Chairman.

Mr. BROWN. Since he has accepted a higher position as Deputy Administrator of EPA. I will use this occasion to congratulate him on this presumed promotion. I do not know whether it will contribute to improving the quality of his life or not, but certainly his existing position has not been one free from stress and pain. So we hope that the promotion will be some improvement.

Mr. ROBERTS. Would the chairman yield?

Mr. BROWN. I would be happy to yield.

Mr. ROBERTS. I have in my opening statement several paragraphs extolling the virtues of Dr. Moore, as we have gone through our various responsibilities on this subcommittee, and I would like to rather than making that statement, in the interest of time, simply have permission to include my full statement in the record at this point.

Mr. BROWN. Without objection, that will be the order, and of course, I will expand on my remarks about Dr. Moore in the record as well.

[The prepared statement of Mr. Roberts follows:]

OPENING STATEMENT
THE HONORABLE PAT ROBERTS
HEARING ON
H.R. 4937, "PESTICIDE FOOD SAFETY ACT OF 1988

Mr. Chairman, thank you very much for scheduling this important hearing today. We cannot shy away from the complex and arcane provisions of the laws at issue today. The matters of food safety and pesticide regulation are, and should be, a high priority for the agriculture community.

The regulations, laws, and the agencies that govern the manufacture, sale, and use of pesticides do not carry with them the public's confidence. As a direct consequence, people fear pesticides as they are now used in crop production, for the control of pests at work and home, and to preserve the value of our nation's woodlands. This paucity of confidence offers an enticing target for advocacy groups and politicians who constantly denigrate the safety of our food supply for their own purposes. The Subcommittee on Department Operations, Research, and Foreign Agriculture (DORFA) sits at the intersection of these complex issues. I firmly believe we have the jurisdictional tools to unify the regulatory patchwork governing the use of pesticides, and provide for the consistent regulation of pesticides wherever they are used in our environment.

For the last seven years, and as ranking minority member of the DORFA Subcommittee, I have strained to sort through and help resolve the pest control and food safety problems facing our nation. The DORFA Subcommittee has conducted innumerable oversight hearings into how existing law and policy should be changed to help EPA and FDA do a better job of protecting the public health. We have drafted, debated, and passed a substantial body of legislation, very little of which has become law.

In May of 1987, the National Academy of Sciences (NAS), released a report, "Pesticide Residues in Food: the Delaney Paradox." This report details the extent of the regulatory gridlock now trapping EPA due to the disconnect between two statutes -- the principal pesticide regulatory law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug, and Cosmetic Act (FDCA), the main statute governing the safety of food products, drugs, and medical devices. EPA cannot employ consistently rational standards of risk when setting pesticide tolerances for various foods. Despite these problems in the abstract, the authors of the report confirmed in no uncertain terms a consistently ignored fact -- no other nation can match the marvel of the United States food supply, in quantity, soundness, or safety.

The NAS report made several conclusions and recommendations which constitute the intention of H.R. 4937. I would like to reiterate two of the reports most pertinent insights:

Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current laws and regulations governing residues in raw and processed food are inconsistent with this goal, (p. 11).

A negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits, (p. 12).

I am confident that the implementation of the NAS report's recommendations would garner EPA and FDA a higher, broader, level of public confidence for their regulatory decisions.

Mr. Chairman, I am delighted -- indeed proud -- you agreed to join me in co-sponsoring H.R. 4937, "The Pesticide Food Safety Act of 1988," a bill that I believe goes straight to the heart of the problems that have so often frustrated us. Let me also say I sincerely look forward to further discussion and review of another important bill addressing this topic introduced just a month ago by our colleague and friend from California, Congressman Henry Waxman. Mr. Waxman and his colleagues have also conducted in-depth hearings over many years on these problems, and his bill contains a number of significant new proposals for changes in regulatory policy that deserve a careful assessment in the context of FIFRA.

I am also anxious to hear from Dr. Jack Moore, EPA's very able Assistant Administrator for Pesticides and Toxic Substances and soon to assume the responsibilities of Acting Deputy Assistant Administrator. With his leadership, EPA deserves credit for recognizing the need to act on these issues. First, by initiating the May 1987 NAS report, and secondly, by developing an action plan to implement the report. We in the agriculture community eagerly await the unveiling of that plan and want to assist the agency in the discharge of its regulatory responsibilities.

Mr. Chairman, the purpose of H.R. 4937 is twofold: to implement the NAS report with respect to pesticide registration and tolerance setting, and to accelerate USDA's research and extension efforts in integrated pest management (IPM). A renewed national commitment to IPM, the content of Title III of my bill, is clearly the best way the government can begin to help free our farmers from the recurrent threat of economic disaster brought on by unanticipated, unpredictable chemo-phobia, which is only rarely justified by a scientifically sound assessment of pesticide risks.

The pesticide tolerance provisions in Title II of the bill propose no major overhaul of the FDCA. In keeping with the NAS report, these provisions straight forwardly provide for the consistent regulation of pesticide residues for all food products.

The NAS panel pointed out that pesticide residues which concentrate in processed food are regulated under section 409 of the FDCA. Section 409 permits absolutely no consideration of a pesticide's benefits, even if they are extraordinarily high, and without exception prohibits tolerances for pesticides that have been found to induce cancer in man or animal, even when the risk of cancer, from a scientific perspective, is essentially nil.

Pesticide residues on raw agricultural commodities, on the other hand, are regulated under section 408 of the FDCA, which permits consideration of benefits, as well as the actual safety of a pesticide.

The NAS panel also determined that the consistent application of a one in a million standard of safety, known as negligible risk, for all oncogenic pesticides -- new and old -- and to all forms of food, could dramatically reduce dietary exposure to potential carcinogens with modest loss of benefits. My bill implements this finding by establishing under section 408 a consistent standard of safety for pesticide chemicals, which according to validated tests and other evidence raise prudent concerns of oncogenic risk. Also, the bill firmly positions all pesticides on the same regulatory plane, providing for the equal treatment of old and new chemicals.

For example, Title I, assures that a reregistration of an older pesticide under FIFRA is the functional equivalent of an initial registration for a new pesticides, and it mandates that sound scientific data needed to carry out risk assessments on both new and old pesticides will be submitted to the agency and reviewed in a timely manner.

In other words, my bill eliminates the bias against new chemicals by requiring applicants of reregistration to sustain the same burden, based on equally complete and modern data, as applicants for a new registrations.

The negligible risk concept of Title II of the bill is patterned on the risk standard applied by FDA in regulating the safety of food additives. FDA has concluded that it is possible, using conservative methods of quantitative methods of risk assesment and taking into account all relevant scientific evidence, to identify levels of exposure to oncogenic residues that are safe under the protective standard embodied in the FDCA's section 409. It is, of course, never possible to establish scientifically the absolute absence of risk for any food substance or, for that matter, any chemical exposure or other human activity. FDA's judgement, however, is that upper-bound risks of one in a million over the lifetime of the exposed population, when calculated using currently accepted, conservative methods of risk assesment, is the functional equivalent of no risk at all. That is the concept adopted in this bill.

In its final recommendation, the NAS panel pointed out that much of the potential exposure to oncogenic residues in processed food is concentrated among a relatively small number of compounds, many of which were registered prior to 1978. The subsequent advances of technology available to pesticide regulators, and more stringent standards of risk suggest that the safety data for these older chemicals should be reviewed. The panel thus recommended that EPA focus its energies on reducing actual and potential risks from the most worrisome pesticides on the most consumed crops. My bill helps EPA in this area by specifically authorizing the Agency to promulgate tolerances posing somewhat greater than negligible risk if such action allows the Agency to substantially reduce other risks to man or the environment posed by another, frequently older pesticide chemical used to control the same pest on the same crop. The bill also helps by more fully integrating the food safety provisions of FIFRA and the FDCA. In fact, it goes further by mandating important changes in the reregistration process which should finally provide EPA the tools and authorities needed to bring the persistent backlog of older pesticides into compliance with contemporary scientific risk assessment methods and health protection standards.

Lastly, H.R. 4937 acts on another unmistakable reality. Mother nature and her pests will continue to challenge producers for the very food on our table. This bill authorizes an important new integrated pest management research and education initiative targeted toward crops that may be minor in terms of acreage grown, but which can be major in terms of a balanced, healthy diet, as well as potential dietary exposure to residues in food.

Mr. Chairman, in the eyes of our farm organizations and the individual producer, nothing is more important than the confidence of the consumer in the safety of our food supply. As a farm state Congressman, no prospect worries me more than the notion that the fear of pesticide residues would or could determine the kinds of foods purchased at the local grocery store.

I view the NAS report as a watershed study and a blueprint for change in the processes and policies governing pesticide residues. The agriculture community should embrace the report and encourage the elevation of safety standards through the rational and consistent regulation of pesticide residues.

Mr. BROWN. While we have had our occasional differences, he has made an outstanding contribution in his role as Assistant Administrator for Pesticides and Toxic Substances, and his relationship with at least this part of the Congress has been extremely good. So with these words, you may proceed, Dr. Moore.

[H.R. 4937 follows:]

100TH CONGRESS
2D SESSION

H. R. 4937

Entitled the "Pesticide Food Safety Act of 1988".

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 1988

Mr. ROBERTS (for himself and Mr. BROWN of California) introduced the following bill; which was referred jointly to the Committees on Agriculture and Energy and Commerce.

A BILL

Entitled the "Pesticide Food Safety Act of 1988".

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Pesticide Food Safety Act
4 of 1988".

5 SEC. 2. EFFECTIVE DATE.

6 Except as otherwise specified in any other provision of
7 this Act, the amendments made by titles I, II, and II of this
8 Act shall take effect on the enactment of this Act.

1 **TITLE I—PESTICIDE REGISTRATION**2 **SEC. 101. REFERENCE.**

3 Whenever in this title an amendment or repeal is ex-
 4 pressed in terms of an amendment to, or repeal of, a section
 5 or other provision, the reference shall be considered to be
 6 made to a section or other provision of the Federal Insecti-
 7 cide, Fungicide, and Rodenticide Act.

8 **SEC. 102. REREGISTRATION OF PESTICIDES.**

9 Section 3 (7 U.S.C. 136a) is amended as follows:

10 (a) Amend subsection (g) to read as follows:

11 “(g) **REREGISTRATION OF PESTICIDES.**—

12 “(1) **RESPONSIBILITIES OF REGISTRANTS AND**
 13 **ADMINISTRATOR.**—It shall be the responsibility of
 14 each registrant to apply for the reregistration of his
 15 pesticide within the time period provided in paragraph
 16 (3) or (4), as appropriate. The Administrator shall
 17 review the data after receipt of the application and
 18 shall, as expeditiously as possible, but not later than
 19 the date provided in paragraph (3) or (4), as appropri-
 20 ate, either reregister the pesticide in accordance with
 21 subsection (c)(5), or notify the registrant of his determi-
 22 nation that it does not comply with the provisions of
 23 the Act in accordance with subsection (c)(6): *Provided,*
 24 That the Administrator shall permit sufficient time for
 25 applicants to obtain any requested additional informa-

1 tion. In reviewing an application for reregistration of a
2 pesticide under this paragraph, the Administrator shall,
3 at the same time, consider the adequacy of regulations
4 promulgated for such pesticide under the Federal Food,
5 Drug, and Cosmetic Act.

6 “(2) DENIAL HEARINGS.—In the event a hearing
7 is requested following issuance of a notice of denial
8 under subsection (c)(6), the registration of the pesticide
9 whose reregistration is the subject of the notice of
10 denial shall be permitted to continue in effect until the
11 Administrator makes a final decision under section 6(b),
12 except that the Administrator shall remain free to initi-
13 ate appropriate action to suspend such registration
14 under section 6(c) or section 3(c)(2)(B) of this Act: *Pro-*
15 *vide*, That the denial hearing shall be completed and
16 the Administrator shall make a final decision within
17 three hundred and sixty days after issuance of the
18 notice that gave rise to the hearing. The time limit im-
19 posed by this paragraph may not be extended, except
20 in exceptional circumstances in which such extension is
21 essential for a fair and accurate determination of pivot-
22 al facts central to the proceeding. In no event may
23 such time limit be extended more than one hundred
24 and eighty days. Failure to complete a hearing and
25 make a final decision within the time period prescribed

1 by this paragraph shall be grounds for a civil action in
2 a district court of the United States seeking an order
3 to establish a schedule requiring the prompt completion
4 of the hearing, but shall not be grounds for termination
5 of the hearing or for making a final decision respecting
6 the pesticide that is the subject of the hearing.

7 “(3) POST-1978 REGISTRATIONS.—With respect
8 to pesticides containing active ingredients that are ini-
9 tially registered or reregistered under this Act after
10 September 30, 1978, a complete application for rereg-
11 istration shall be submitted no later than at the end of
12 the eleven-year period which begins on the date of its
13 last registration or reregistration, and the Administra-
14 tor shall act on such applications no later than at the
15 end of the twelve-year period which begins on such
16 date, except that for pesticides registered as of the ef-
17 fective date of this Act, the application for reregistra-
18 tion shall be submitted by the date provided in this
19 paragraph or by December 31, 1994, whichever is
20 later, and the Administrator shall act on such applica-
21 tions by the date provided in this paragraph or by
22 December 31, 1995, whichever is later.

23 “(4) PRE-1978 REGISTRATIONS.—With respect
24 to pesticides containing active ingredients that were
25 initially registered under this Act on or before Septem-

1 ber 30, 1978, a complete application for reregistration
2 shall be submitted when required by the Administrator,
3 but in any event no later than December 31, 1994,
4 and the Administrator shall act on such applications
5 within one year of the date of submission, but in any
6 event no later than December 31, 1995: *Provided,*
7 That, to the extent appropriate, any pesticide that re-
8 sults in a post-harvest residue in or on food or feed
9 crops or in a residue in or on processed food shall be
10 given priority in the reregistration process.

11 “(5) REREGISTRATION AS FUNCTIONAL EQUIVA-
12 LENT OF REGISTRATION.—For all purposes under this
13 Act, the reregistration of a pesticide shall be the func-
14 tional equivalent of the registration of a pesticide, in-
15 cluding registration under special circumstances under
16 subsection (c)(7).

17 “(6) FUNDING.—To implement the program of re-
18 registration under this subsection, there are authorized
19 to be appropriated such sums as may be necessary for
20 each fiscal year beginning on October 1, 1988 through
21 September 1995.”.

22 (b) Add at the end thereof the following new subsection
23 (h):

24 “(h) FOOD USE PESTICIDES.—In making any determi-
25 nation under this Act concerning unreasonable adverse ef-

1 fects on the environment of any pesticide that results in a
2 post-harvest residue in or on food or feed crops or in a resi-
3 due in or on processed food, the Administrator shall consider
4 the ways in which the consumer may be affected by such
5 residues and any other ways in which the consumer may be
6 affected by the same pesticide.”.

7 SEC. 103. CANCELLATION.

8 Section 6(a) (7 U.S.C. 136d(a)) is amended to read as
9 follows:

10 “(a) SPECIAL RESPONSIBILITIES AND AUTHORI-
11 TIES.—

12 “(1) CANCELLATION AFTER EXPIRATION OF
13 PERIOD FOR REREGISTRATION.—The Administrator
14 shall cancel the registration of any pesticide at the end
15 of the applicable period provided under section (3)(g) of
16 this Act unless the registrant, or other interested
17 person with the concurrence of the registrant, before
18 the end of such period submits a timely application for
19 reregistration as required thereunder. The Administra-
20 tor shall publish in the Federal Register, at least
21 ninety days prior to the expiration of such period,
22 notice that the registration will be canceled unless the
23 registrant or other interested person with the concu-
24 rence of the registrant can establish, in accordance
25 with regulations prescribed by the administrator, that a

1 timely application for reregistration has been
2 submitted.

3 “(2) INFORMATION.—If at any time after the reg-
4 istration or reregistration of a pesticide the registrant
5 has additional factual information regarding unreason-
6 able adverse effects on the environment of the pesti-
7 cide, he shall submit such information to the Adminis-
8 trator.

9 “(3) EXISTING STOCKS.—The Administrator may
10 permit the continued sale and use of existing stocks of
11 a pesticide whose registration is canceled or whose re-
12 registration is denied under this Act to such extent,
13 under such conditions, and for such uses as the Admin-
14 istrator may specify if the Administrator determines
15 that such sale or use is not inconsistent with the pur-
16 poses of this Act and will not have unreasonable ad-
17 verse effects on the environment: *Provided*, That in no
18 event shall the continued sale of a pesticide be allowed
19 for more than one year after the effective date of a
20 cancellation or denial notice or order issued under this
21 section, except that the Administrator may, in extraor-
22 dinary circumstances, extend this period if the Admin-
23 istrator deems such extension to be in the public
24 interest.

1 **TITLE II—PESTICIDE RESIDUES**2 **SEC. 201. REFERENCE**

3 Whenever in this title an amendment or repeal is ex-
4 pressed in terms of an amendment to, or repeal of, a section
5 or other provision, the reference shall be considered to be
6 made to a section or other provision of the Federal Food,
7 Drug, and Cosmetic Act.

8 **SEC. 202. DEFINITIONS.**9 **(a) PESTICIDE.—**

10 (1) Section 201(q) (21 U.S.C. 321(q)) is amended
11 to read as follows:

12 “(q) The term ‘pesticide chemical’ means any substance
13 which alone, or in chemical combination with, or in formula-
14 tion with one or more other substances, is a “pesticide”
15 within the meaning of the Federal Insecticide, Fungicide, and
16 Rodenticide Act (7 U.S.C. 136 et seq.), and which is used in
17 the production, storage, or transportation of a raw agricultur-
18 al commodity or processed food. The term may include, as
19 deemed appropriate by the Administrator, any active or inert
20 ingredient of a pesticide or any substance present in or on a
21 raw agricultural commodity or processed food as a result of
22 the metabolism or other degradation of a pesticide.”.

23 (2) Section 201(s)(1) (21 U.S.C. section 321(s)(1))
24 is amended to read as follows:

1 “(1) a pesticide chemical in or on a raw agricul-
2 tural commodity or processed food; or”.

3 (3) Section 201(s)(2) (21 U.S.C. section 201(s)(2))
4 is amended to read as follows:

5 “(2) a pesticide chemical to the extent that it is
6 intended for use or is used in the production, storage,
7 or transportation of any raw agricultural commodity or
8 processed food; or”.

9 (b) **OTHER DEFINITIONS.**—Section 201 (21 U.S.C.
10 321) is amended by adding at the end thereof the following:

11 “(bb) The term ‘processed food’ means any food other
12 than a raw agricultural commodity.

13 “(cc) The term ‘Administrator’ means the Administrator
14 of the Environmental Protection Agency.”.

15 **SEC. 203. ADULTERATED FOOD.**

16 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended to
17 read as follows:

18 “(2)(A) if it bears or contains any added poisonous
19 or added deleterious substance (other than one which is
20 (i) a pesticide chemical, (ii) a food additive, (iii) a color
21 additive, or (iv) a new animal drug) which is unsafe
22 within the meaning of section 406;

23 “(B) if it bears or contains a pesticide chemical
24 which is unsafe within the meaning of section 408(a);

1 “(C) if it is, or it bears or contains, any food addi-
 2 tive which is unsafe within the meaning of section 409;
 3 or

4 “(D) if it is, or it bears or contains, a new animal
 5 drug (or conversion product thereof) which is unsafe
 6 within the meaning of section 512; or”.

7 **SEC. 204. TOLERANCES OR PESTICIDE CHEMICALS.**

8 Section 408 (21 U.S.C. 346a) is amended as follows:

9 (a) Amend the title of the section to read as follows:
 10 “TOLERANCES FOR PESTICIDE CHEMICALS”.

11 (b) Insert the phrase “or processed food” immediately
 12 following the phrase “raw agricultural commodity” wherever
 13 it appears throughout the section, and insert the phrase “or
 14 processed foods” immediately following the phrase “raw ag-
 15 ricultural commodities” wherever it appears in subsections
 16 (b) and (c).

17 (c) Amend subsection (a) by inserting after “added to”
 18 the following: “or present in”.

19 (d) Amend subsection (a)(2) by inserting after “with re-
 20 spect to use” the following: “or presence”.

21 (e) Amend subsection (b) to read as follows:

22 “(b)(1) The Administrator shall promulgate regulations
 23 establishing, modifying, or revoking tolerances with respect
 24 to the use or presence in or on raw agricultural commodities
 25 or processed foods of poisonous or deleterious pesticide

1 chemicals and of pesticide chemicals which are not generally
2 recognized, among experts qualified by scientific training and
3 experience to evaluate the safety of pesticide chemicals, as
4 safe for use, to the extent necessary to protect the public
5 health: *Provided*, That for pesticide chemicals found by the
6 Administrator to raise prudent concerns of oncogenic risks on
7 the basis of a validated test and other evidence, such toler-
8 ance shall not be established or left in effect above a level
9 that the Administrator deems to be associated with a negligi-
10 ble risk to human health, except as otherwise provided under
11 paragraph (2) of this subsection. In establishing any such reg-
12 ulations, the Administrator shall, consistent with paragraph
13 (2) of this subsection, give appropriate consideration to the
14 risks and benefits of such action including, among other rele-
15 vant factors—

16 “(A) the necessity for the production of an ade-
17 quate, wholesome, and economical food supply;

18 “(B) the other ways in which the consumer may
19 be affected by the same pesticide chemical, including
20 its presence in or on other raw agricultural commod-
21 ities and processed foods, or by related substances that
22 are poisonous or deleterious; and

23 “(C) to the opinion submitted with a certification
24 of usefulness under subsection (1) of this section.

1 Such regulations shall be promulgated in the manner pre-
2 scribed in subsection (d) or (e) of this section. Any regulation
3 establishing or modifying a tolerance may contain a provision
4 setting an expiration date for the tolerance. In carrying out
5 the provisions of this section relating to the establishment of
6 tolerances, the Administrator may establish the tolerance at
7 zero level if the scientific data before the administrator does
8 not justify the establishment of a greater tolerance.

9 “(2) For pesticide chemicals found by the Administrator
10 to raise prudent concerns of oncogenic risks on the basis of a
11 validated test and other evidence, the Administrator may es-
12 tablish a tolerance or allow a tolerance to remain in effect
13 above a level associated with a negligible risk to human
14 health if, after giving appropriate consideration to the factors
15 in paragraph (1) of this subsection, the Administrator—

16 “(A) finds, on the basis of data submitted by the
17 petitioner under subsection (d) or by other interested
18 persons, clear and convincing evidence that the benefits
19 to consumers associated with such a tolerance in terms
20 of an adequate, wholesome, and economical food
21 supply outweigh the risks, or

22 “(B) takes appropriate action under this section,
23 to substantially reduce the dietary risks associated with
24 the use of an alternative pesticide chemical for control
25 of the same pest on the same crop, where such alterna-

1 tive pesticide chemical poses greater risks than the
2 first: *Provided, That, to the greatest extent possible,*
3 determinations with respect to the relative risks of pes-
4 ticide chemicals under this paragraph shall be based on
5 actual usage of the pesticide chemicals and on residue
6 levels anticipated routinely in or on raw agricultural
7 commodities or processed foods, or

8 “(C) takes appropriate action under the Federal
9 Insecticide, Fungicide, and Rodenticide Act to substan-
10 tially reduce the risks to humans or the environment
11 associated with the use of an alternative pesticide
12 chemical for control of the same pest on the same crop,
13 where such alternative pesticide chemical poses greater
14 risks than the first: *Provided, That, to the greatest*
15 *extent possible, determinations with respect to the rel-*
16 *ative risks of pesticide chemicals under this paragraph*
17 *shall be based on actual usage of the pesticide chemi-*
18 *cals and, where applicable, on residue levels anticipat-*
19 *ed routinely in or on raw agricultural commodities or*
20 *processed foods.*

21 “(3) Notwithstanding the provisions of subsection (a) of
22 this section, where a pesticide chemical has been used in or
23 on a raw agricultural commodity in conformity with an ex-
24 emption granted or a tolerance prescribed under this section
25 and such raw agricultural commodity has been subjected to

1 processing such as canning, cooking, freezing, dehydrating,
2 or milling, the residue of such pesticide chemical remaining in
3 or on such processed food shall not be deemed to be unsafe
4 within the meaning of section 402(a)(2)(B) despite the lack of
5 a tolerance or exemption for the pesticide chemical in or on
6 the processed food, if such residue in or on the raw agricul-
7 tural commodity has been removed to the extent possible in
8 good manufacturing practice and the concentration of such
9 residue in the processed food when ready to eat is not greater
10 than the tolerance prescribed for the raw agricultural
11 commodity.”.

12 (f) Amend subsection (c) to read as follows:

13 “(c) The Administrator shall promulgate regulations ex-
14 empting any pesticide chemical from the requirement of a
15 tolerance when such a tolerance is not necessary to protect
16 the public health, and shall modify or revoke such an exemp-
17 tion to the extent necessary to protect the public health. Such
18 regulations shall be promulgated in the manner prescribed in
19 subsection (d) or (e) of this section.”.

20 (g) Revise subsection (k) thereof to read as follows:

21 “(k) Regulations affecting pesticide chemicals in or on
22 raw agricultural commodities which are promulgated under
23 the authority of section 406(a) upon the basis of public hear-
24 ings instituted before January 1, 1953, in accordance with
25 section 701(e), and regulations affecting pesticide chemicals

1 in or on processed foods which are promulgated under the
 2 authority of section 409 before the date of the enactment of
 3 this Act shall be deemed to be regulations under this section
 4 and shall be subject to amendment or repeal as provided in
 5 subsection (m).”.

6 TITLE III—INTEGRATED PEST MANAGEMENT

7 SEC. 301. SHORT TITLE.

8 This title may be cited as the “National Agricultural
 9 Research, Extension, and Teaching Policy Act Amendments
 10 of 1988”.

11 SEC. 302. TARGETED INTEGRATED PEST MANAGEMENT INITIA- 12 TIVE.

13 (a) The National Agricultural Research, Extension, and
 14 Teaching Policy Act Amendments of 1985 is amended as
 15 follows:

16 (1) Amend section 1402(8) by adding a new para-
 17 graph (Q) to read as follows:

18 “(Q) the development of integrated pest man-
 19 agement techniques with a special focus on fruit
 20 and vegetable crops critical to a balanced, healthy
 21 diet which are considered as minor crops in terms
 22 of acreage produced.”.

23 (2) Amend section 1405 by adding a new subsec-
 24 tion (13) to read as follows:

1 “(13) establish within the office of the Administra-
2 tor of the Environmental Protection Agency a commit-
3 tee to oversee coordination between the Department of
4 Agriculture’s conservation, commodity, research and
5 education programs and the Environmental Protection
6 Agency’s pesticide regulatory activities. The committee
7 shall include scientists and program officials from the
8 United States Department of Agriculture and Environ-
9 mental Protection Agency; one representative from
10 each of the following: the President’s Office of Science
11 and Technology Policy, the President’s Council on En-
12 vironmental Quality, and the National Science Founda-
13 tion; and representatives of State agencies with respon-
14 sibility for administering agricultural, natural resources
15 use, and public health protection programs. The com-
16 mittee shall design and oversee an integrated pest
17 management initiative, targeted toward minor use
18 crops that play an important role in the human diet.
19 The initiative shall focus on developing economical pest
20 control techniques, and the reduction of pesticide resi-
21 dues associated with traditional production practices for
22 minor crops when, in the judgment of the committee,
23 such reduction may lessen dietary risk from pesticide
24 residues.”.

1 IPM research and education initiatives targeted toward prin-
2 cipal pests of minor crops. The committee shall report to
3 Congress annually by February 28, or as part of the Presi-
4 dent's budget submission, regarding the activities of the com-
5 mittee, its findings and recommendations regarding needed
6 priority areas of research, the adequacy of current levels of
7 funding, and steps taken in the President's budget request to
8 provide adequate funds to undertake high priority research
9 initiatives. The committee shall also report on the commit-
10 tee's findings and recommendations in other areas of policy,
11 or other agricultural or regulatory programs which warrant
12 attention by the Congress in advancing the rate of progress
13 in the adoption of profitable on-farm use of safer, efficient
14 pest control methods and technologies.

15 “(c) The interagency committee shall offer advice to the
16 Administrator regarding ways to take into account the poten-
17 tial implications of the emergence or severity of genetic re-
18 sistance in pest populations to pesticides, and/or the viability
19 and profitability of IPM systems with regard to registration,
20 reregistration, and cancellation actions. These factors shall
21 also be considered by the Secretary in administering agricul-
22 tural research and teaching programs under this title.

23 “(d) The Secretary and Administrator shall jointly de-
24 velop and submit to Congress within 18 months of the date of
25 enactment of this Act studies of—

1 “(1) public policy and programmatic barriers to
2 adoption of IPM by farmers, with special focus on cur-
3 rent commodity, conservation, and other agricultural
4 program provisions in place under the Food Security
5 Act of 1985; and options within agricultural commodi-
6 ty and conservation programs to foster broader adop-
7 tion of IPM systems and other management practices;
8 and

9 “(2) extending coverage under the Federal Crop
10 Insurance Program to cover pest losses suffered by
11 farmers applying recommended IPM techniques when
12 such losses are determined to result from unanticipated
13 natural and biological events that unavoidably reduce
14 the effectiveness of IPM practices.

15 “(e) To implement the program of research and educa-
16 tion under this subtitle, there are authorized to be appropri-
17 ated \$25,000,000 for each fiscal year beginning October 1,
18 1988, through September 1994.”.

19 (b) Section 2(b) of the Act of August 4, 1965 (79 Stat.
20 431; 7 U.S.C. 450i), is amended by adding a new paragraph
21 (9) to read as follows:

22 “(9) research to develop and refine integrated pest
23 management techniques, and other pest control tech-
24 nologies targeted toward major pests of minor use
25 crops, particularly those pests and crops which require

- 1 applications of pesticides that may pose greater than
- 2 negligible risks to man or the environment.”.



STATEMENT OF JOHN MOORE, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. MOORE. Thank you, Mr. Chairman. In the interest of your abbreviated schedule this morning, with your indulgence, I will just focus on one of the titles of the bill, the title II section. Title II of this bill is designed to eliminate two major problems in the current Federal Food, Drug, and Cosmetic Act.

Clearly we have different standards, depending upon the fortuity of whether the residues are found in raw foods or in processed foods. In addition, the other issue is that Section 409 standards for pesticide residues in processed foods in our opinion clearly conflicts with the pesticide registration standards found in the Federal Insecticide, Fungicide, and Rodenticide Act.

In essence, H.R. 4937 would adopt the gist of the two National Academy of Sciences recommendations that were found in their report of a year ago. It would bring all regulation of pesticide residues under one set of standards, section 408 of the act.

It would also regard negligible risk as the appropriate standard for establishing the point of reference, if you will. EPA strongly supports these approaches, as we have strongly supported the major recommendations in the Academy report. I think we also cannot lose sight of the fact that section 408 of this act has not been amended appreciably since 1954.

I think it is important to open up the tolerance setting process in 1988 to increase public access and input, while avoiding undue delay, and identify and address specific scientific concerns raised by environmental and consumer organizations.

My reason for pointing that out is that I think something must be done to increase the public's confidence in the Federal pesticide regulatory system and correspondingly, to hopefully decrease the calls for State and local regulation that could destruct the interstate marketing of food.

I think the law also should provide uniform procedures that would govern the rights and duties of all persons who request EPA to issue, modify, or revoke a tolerance or exemption. And should state clearly the administrative and judicial review rights of all such persons or parties.

In addition, I think EPA should be authorized to require the submission of data needed to justify the continuation in effect of an existing tolerance or exemption. And should be authorized to revoke a clearance promptly if the required data is not forthcoming.

Lastly, I think the law should set forth rules for deciding whether food may be lawfully shipped and sold if it contains residues that were lawful at the time the pesticide was applied but later were subject to a tolerance revocation process, sometimes referred to as the pipeline issue.

Many of the matters that I think this bill is silent on are addressed at least in H.R. 4739, introduced by Congressman Waxman, and I have testified on those points as well.

However, while that bill addresses issues that I think are highly appropriate in 1988, the bill is also very problematic in several :

spects, particularly in regards to the highly prescriptive nature it takes as opposed to decisionmaking.

In conclusion, let me say that Title II of H.R. 3947 contains a number of provisions that I and the agency support although there are changes needed that this bill does not address. We certainly would be glad to work with you and other members of Congress on discussing and hopefully resolving these issues.

[The prepared statement of Mr. Moore appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Moore. As you have pointed out, the instigation or impetus for this legislation stems from a National Academy report of a year ago, which raised the question of negligible risks as compared to the existing standard contained in the Food, Drug and Cosmetic Act of zero tolerance.

I wonder if you would elaborate just very briefly on the differences between these two approaches? What are we talking about when we talk about negligible risk?

Mr. MOORE. Well, as you know, Mr. Chairman, the Academy introduced or legitimized the term "negligible risk" in its report and alluded to the fact that such risk might be around a lifetime risk of one in a million increased risk of cancer.

The bill introduced by Congressman Waxman uses the term "negligible risk" but it then goes on to define in great detail exactly what happens or does not happen based on this one in a million risk. It also tells us how to calculate it in a highly prescriptive way.

My concern is that this is an area, I think, of fluid science. There is a lot of information being brought to bear that is showing an evolution in how we calculate such findings. And as a consequence, if we were to embrace, if you will, a rigid definition and a prescriptive approach, I think we might be unwittingly substituting a new set of problems for the old set of problems that we find in regard to the rigid definition found in the Delaney section of the current section 409.

So I would say that we just are not at a place today where a magic on-off type of signal is appropriate, if only because I do not think we can calculate that one in a million risk or any other number with the degree of precision that this bill would suggest.

In contrast, the bill we are discussing this morning certainly suggests that negligible risk is the approach, but it is silent as to that definition. And while I, as a regulator, might like that since it gives me great leeway, I think a little bit of guidance from Congress in that regard probably would be helpful, but certainly not going as far as the prescriptive approach that is found in the Waxman bill.

Mr. BROWN. I saw recently, and I am a little vague on the details, that EPA was making some effort to get public input or polling data indicating the degree to which the public might accept varying differing standards of risk.

I wonder if you could clarify that for me? As I recall, and I am just trying to recall a newspaper story, there were variations all the way from one in 10,000 to one in a million or better. Can you tell me what the basis for that was?

Mr. MOORE. Well, I think what you are referring to, Mr. Chairman, is the fact that different calculations of risk in a quantitative

sense may well be driving, or may trigger, priority consideration of various types of actions under the varying statutes that the Agency administers.

I might even say within the FIFRA statute, we probably use a different standard. We are much more conservative, if you will, or rigid in our approach as it relates to risks that might be embodied in a residue found in food, and may well be more tolerant of a theoretical calculated risk as it was associated with occupational exposure to the use of pesticides.

The other concern that has received a fair amount of attention is the setting of maximum contaminant levels under the Safe Drinking Water Act. We are trying to integrate MCL's in discussions relating to pesticides in ground water or chemicals in ground water, and in general, trying to embrace again this concept of negligible risk or one in a million risk. If one looks at current regulations where MCL's have been formally established, some of those levels clearly would permit a calculated risk that is greater than one in a million.

Mr. BROWN. How do we integrate the concept of relative benefit into this formula of negligible risk? Or should we get into that?

Mr. MOORE. Well, I think it could easily become a quagmire if one is not careful in that area. One possible approach that could be taken as it relates to pesticide residues in food could be that when one talks about the benefits accruing from the use of that pesticide in suggesting that you might allow a residue which poses a risk greater than a one in a million risk, would be to give better definition, benefit to who? Benefit to the user or benefit to the consumer? Maybe that area is certainly worthy of some consideration and debate leaning toward the wisdom of Congress as to whether it should remain silent or give some specific guidance in that area.

Mr. BROWN. Well, I do not want to get into that too deeply, but I do recall from the National Academy's study that there was postulated the possibility at least that by the uniform application of a negligible risk standard throughout the process of evaluating chemicals, we might result in an overall benefit to consumer health as a result of that rather than the two different standards that we use at the present time.

I am going to recognize Mr. Roberts at this point.

Mr. ROBERTS. Thank you, Mr. Chairman. I am going to follow up the train of thought that you have started here in regards to how significant the Delaney Clause is to public confidence in the safety of our food supply and the adequacy and reliability of our whole regulatory processes in this regard.

And I am just going to ask you a very subjective question. Do you think that legislation modifying the application of the Delaney Clause and lessening the problem, as we believe, that is associated with zero risk would receive a negative reaction, not so much by the various organizations and groups that oppose this on the surface of it, but by the State-regulatory agencies and encourage them to apply their own zero risk standards for pesticides?

Mr. MOORE. Congressman, in my discussions with State officials on this general issue, my sense would be that if one moved away from our current situation and moved to a uniform application involving whether it be processed foods or raw agricultural commod-

ities and came up with a defined point of reference, whether it be negligible risk or something else, that from their perspective I do not think that would prove to be problematic.

As the Academy report points out, the current system that we have is illogical from a scientific basis. There is no reason why you should have a variance in the amount of residue you would allow in a raw product as opposed to a processed product if, indeed, the objective that you are looking at in reviewing those levels is controlling the amount of residue in the food that we eat.

I mean we eat both. So why should we have a differing approach?

Mr. ROBERTS. Well, I quite agree from a scientific standpoint, but from a political standpoint in the best sense of the word in terms of public perception and the pressures that would bear on the State-regulatory agencies, I am concerned about that. I do not want to see a situation where we have 50 proposition 65's, or whatever number we want to assign this, based on this particular issue, when we are trying to bring a greater understanding to consumers all across the country.

You mentioned that science is in a fluid state, and used that description in regards to a rather rigid regulatory approach, and that those two approaches would not be compatible, and that leads me to my next question. Do you believe that a numerical definition of a negligible risk standard should be codified by law?

Mr. MOORE. I think it could be very problematic to come up with a rigid definition, numerical definition in any statute, no matter what the number is, whether it be one in a million or something else. I think what might be appropriate, however, is to identify quantitatively a number, but allow some degree of flexibility around that number. For example, a risk of one in 999,999 if you set one in a million as a trigger point is quote "not safe"? And a risk of one in 1,000,001 is "safe"? It is—you know, it is illogical.

Mr. ROBERTS. Well, as I think you are aware, that is the basic difference between the bill that we have introduced in this subcommittee and the bill introduced by our colleague and friend from California, Mr. Waxman. And to what degree we have that flexibility to make the risk standard workable seems to me to be one of the primary issues that we have to settle before this legislation moves out of the subcommittee level and into full committee consideration.

Let me change the subject. I do not think there is any question that everybody in this room is awaiting the unveiling of your plan in regard to the NAS report. And we ask you that every time you come up here. What is the status of that plan?

Mr. MOORE. It is still in review, prior to coming out, over at OMB.

Mr. ROBERTS. Are we ever going to get that plan to the senior prom?

Mr. MOORE. I think so.

Mr. ROBERTS. OK. And in relation to that, do you believe that current law gives you the authority to implement most of the report's recommendations? And I will add another question. And does the report assume the Agency has this authority or do we have to come up with some authorization for you to do this job?

Mr. MOORE. Congressman, without getting into detail, our plan, I think I can say, is attempting to identify an approach to implement the Academy recommendations, and we clearly articulate in that plan where we think we cannot go as far as the plan would recommend, based on the limitations of the current statute.

And that particularly is some of the limitation associated with section 409.

Mr. ROBERTS. You made a statement on May 20, 1987, and before the Senate Ag Committee in regard to the Delaney Clause where you said,

Through our data call-in and registration standards program, we have been calling in the necessary data to support the tolerance reassessments on individual chemicals. And we are now receiving the data necessary to make tolerance reassessment decisions on a number of existing chemicals.

The question I would pose to you do you think that pesticide reregistration and tolerance reassessment should occur simultaneously or do these regulatory processes best work independently of each other? Obviously, title I of the bill that we have introduced involved reregistration.

And there has been considerable discussion as to whether or not that should be included in the negligible risk bill. Would you respond to that?

Mr. MOORE. Yes. I do not think it is wise to have a process that requires that it be done sequentially because what you will end up with is identifying a potential problem, but then the problem still sits there while you in a sequential fashion try to get the residue data that hopefully will resolve the issue.

So I would say that there probably is a need for either simultaneous requirements of data or at least if there are, for example, three phases in reregistration under FIFRA, that after Phase I is completed you could then kick in, based on that information, the requirements for residue data.

We do not need a wholesale resubmission or initial submission of residue data on all crops or all tolerances on all crops. For example, if the data come up showing that, indeed, there is no risk at all, even at very high levels of residue, there is no sense in asking the industry to provide data telling you what those levels are since we know even with crude information that there is no problem.

Mr. ROBERTS. Let me point up what may be obvious in this particular instance, and that is that the Waxman bill does not seem to me to marry the two processes. That it effectively, I guess, just obviates the bulk of the need for the reregistration of food use pesticides.

And that may have some bearing on jurisdiction and feeling on this committee in reference to FIFRA. I do not know if you have any comments about that but I am making that as a statement rather than as a question.

Mr. MOORE. I think there is appeal to having data requirement authority under FFDCA or authority residing elsewhere than just under FIFRA as we currently know FIFRA. FIFRA basically gives me authority to demand data from registrants. And I think if you had some language under FFDCA you could demand data as a requirement for continuing a tolerance. And that data would then have to be generated by whoever was the party of the interest.

What I am concerned about is, particularly as it gets to minor use crops, that the registrant for pure economic reasons will refuse to submit or commit to the submission of data, when, in fact, either a consortium of small agricultural producers or food processors might be more than willing to do it. I would like to have an access to them rather than just have to totally work through the registrant.

Mr. ROBERTS. I appreciate that argument and would only make the observation and would want to underscore that and to stress it that in regards to committee jurisdiction in FIFRA and the pesticide issue entirely that this subcommittee has a great deal of feeling about that as does, I am sure, Mr. Waxman and members of the Energy and Commerce Committee who are in charge of all things walking, crawling, alive, dead, celestial or earthbound.

We would guard that jurisdiction—I think I can speak for the chairman—much in the same fashion as a wounded panther would guard her young, and if you have ever seen a wounded panther in that position, it is a very determined beast.

Let me say that everybody wants to give you the authority for more timely and broader regulation of pesticides and related chemicals. But we do not ever give you the funds to do the job.

Under the Waxman bill, there is authority to establish fees to cover your costs, and you stated in your testimony before his subcommittee that quote “time frames, when they are given, are impractical and in some cases may be impossible to adhere to.” Also that H.R. 4739 quote, “provides for a significant number of actions to be taken at the Agency’s own initiative.”

How much money do you think you might need to implement the Waxman bill?

Mr. MOORE. I have no number to give you this morning. We will try to come up with an estimate.

Mr. ROBERTS. But obviously it is bigger than a bread box and it is significant?

Mr. MOORE. Significant. Very significant.

Mr. ROBERTS. And then following that, as I pause, in terms of amendments to FFDCA, do you view title II of my bill as costing less and being less burdensome on agency resources?

Mr. MOORE. It is conceivable that title II of your bill would cost less. I am not sure it is less burdensome. The burden is in a different place. I think sometimes we are particularly concerned about the bill you have introduced as written, in that it basically is going to compress a tremendous requirement within about a 12 month or 13 month time frame, which probably even if we had tremendous resource would make it unreasonable to expect we could finish.

Mr. ROBERTS. That was done obviously with the full understanding of your recent appointment to the position of authority that you have because we knew we had some strong, responsible people there.

I think at this juncture, Mr. Chairman—well, aside from the issues of funding, and the approach in terms of this bill having obviously more flexibility and Mr. Waxman’s bill obviously more specific, would you care to venture under which bill could you achieve the greatest level of risk reduction?

Mr. MOORE. With the right to revise my opinion with further consideration, I would say that possibly—

Mr. ROBERTS. I thought you were going to say with the right to remain silent until you had an attorney present or something like that.

Mr. MOORE. My initial, my off-the-head reaction would be I think probably with Mr. Waxman's bill.

Mr. ROBERTS. I have no further questions, Mr. Chairman.

Mr. BROWN. Dr. Moore, you have stressed again something that the committee has known, and that is that the mandate of title II of this bill or title I of this bill to accelerate the pace of reregistration is unworkable without the resources, and I want to ask you specifically if the provision for fees that are set forth in the FIFRA reauthorization bill that the subcommittee has already reported out would alleviate this problem substantially, or are we talking here about a level of resources that goes considerably beyond what would be provided in that bill?

Mr. MOORE. Mr. Chairman, if you are referring to the bill you marked up in the last week or two which tracked very closely to the provisions that were in the bill that the Senate Ag came out—

Mr. BROWN. Precisely that is what I am referring to.

Mr. MOORE. We are reasonably satisfied that the resource issue that we are a broken record on would essentially be resolved.

Mr. BROWN. In other words, that would make it possible for you to more readily, at least, carry out the provisions of the bill before us here today?

Mr. MOORE. Yes. I think the estimated cost of reregistration probably does not encompass the totality of some of the things that are being considered under the 408-409 issue, but certainly would cover a portion of those, not a trivial portion.

Mr. Chairman, if I could go back to a line of questioning of a couple of minutes ago dealing with negligible risks, Congressman Roberts asked whether I thought a numerical number should be embodied in the statute, and my answer is probably not. And if you have to do something in that regard, it should be at least a range rather than a precise number.

Perhaps another approach that might be worthy of consideration is for a statute to describe a process whereby we would go through the setting of a number. I am not talking about a prescriptive process, but since science is evolving in this area to somehow describe a process whereby one could be assured that we were consulting all of the appropriate gurus of the time in revisiting or revising what the current number should be. If it has to come to that, maybe such a process is more preferable as a statute rather than come up with a number which is probably going to prove to be wrong, no matter what the number is, probably in a relatively short period of time.

Mr. BROWN. Are you suggesting that we outline in the statute a procedure by which you determine whether a chemical produces tumors in rats, and then how that can be extrapolated to man and so forth, or something less?

Mr. MOORE. Well, I think I am trying to be a realist about it. A number of people are going to be very, I think very ill at ease in

leaving it to the will of the agency without some guidance. That you figure out what negligible risk is and be done with it.

On the other hand, there are obvious problems associated with telling me to the *n*th degree exactly how you will calculate that number. So what I am suggesting is that maybe the statute could direct the Administrator to identify a process whereby all appropriate points of view are participatory in that process in revising and revisiting whatever the standard of the day should be.

Mr. BROWN. Well, I think just off the top of my head, it sounds like it would be desirable to describe a process particularly insofar as it did describe a process allowing for full public participation as well as scientific participation and review.

I am not sure just what language would be necessary, and I hope that you might be willing to suggest, at least, some language under which that might be done. Can we ask you to do that?

Mr. MOORE. Yes, sir.

Mr. BROWN. All right. I am sure Mr. Roberts would like kindly upon including such language in the legislation, or else we could force it on him. Do you have any further comments, Mr. Roberts?

Mr. ROBERTS. As long as it is a risk that is reasonable and negligible, Mr. Chairman. I wanted to go back to this business of this legislation and the legislation introduced by Mr. Waxman and our old friend FIFRA.

It is possible, not probable, but it is possible this year, in fact, that FIFRA and reform of the tolerance setting process could move if not on the same time table more or less in the same general direction.

Do you see any need or benefit to trying to harmonize these two statutes because it seemed to me that one of the basic thrusts of the NAS report was the disconnect, if you will, between negligible risk and the hope to attain that and FIFRA? And I guess I would go ahead and say what aspects of FIFRA and FFDCA deserve attention in this respect?

Mr. MOORE. Congressman Roberts, as you know as well as I, FIFRA is a risk benefits statute. And Congressman Waxman's bill, as we understand it, would make the setting of tolerances, pesticide tolerances, a health risk driven process.

And I do not think as it currently sits, it necessarily reconciles to the satisfaction of this person in EPA or anybody who is going to succeed me as to how you do that because you have a risk benefit statute and you have a risk driven process, according to what he is saying.

To that regard, I think there needs to be some language that does that, or else we find ourselves in a circumstance that is occurring all too frequently in a number of legislative arenas whereby we are in Federal district court in one sort or another being found that we are doing something wrong based on law "x." However, we think we are doing something right based on the FIFRA statute which is law "y," and then when we go to the courts and say, hey, resolve this. It does not make for necessarily wise use of this Nation's resources.

It certainly gives "Excedrin" headaches to the agency, and we have a number of those issues that come up with unfortunately in-

creasing regularity where statutes do not attempt to give some guidance as to how they will interact with other statutes.

Mr. ROBERTS. I can appreciate that. I just also want to stress that it also leads at the initial stages to whose oar is in the pond. Obviously, we feel our pond has to be protected. You have, in essence, indicated that we could take title I and title III out of the Roberts-Brown bill, or the Brown-Roberts bill, and you would have authority to do the job that title II would direct you to do without title I and title III. That is an interesting observation, and I am not sure—do not misunderstand me. We are not going to do that right yet, but at least I can appreciate where you are heading, and it has some rather important aspects we need to study.

I have no further questions, Mr. Chairman. Thank you.

Mr. BROWN. All right. Mr. Moore, I think that is all the questions that we have for you this morning. And if we do need additional input we will send you a letter requesting that, and again, we will appreciate your help in the way that we have previously indicated.

Mr. ROBERTS. Would the chairman yield one more time?

Mr. BROWN. Certainly.

Mr. ROBERTS. I would like to also apologize to the other witnesses in that certainly beyond our control we had the legislative schedule as such that we are considering the drought relief bill. And it involves the attention of both members, and I want to thank them for taking time out of their business schedule to come to this hearing.

And I think perhaps it will work out to our advantage, Mr. Chairman, because now they have had the obvious opportunity to hear Mr. Moore, and may want to comment on his testimony when we have them back up as of next week.

And I do want to encourage them to come and thank them for coming today and apologize for any inconvenience that we may have caused.

Mr. BROWN. Well, let me reiterate that apology. I am afraid that what we are going to have from now on for the rest of the day is a chaotic series of roll calls plus our participation in the debate over there which would make any further effort to continue the hearing rather difficult, to say the least.

Thank you again, Dr. Moore, and we look forward to hearing from you in your new role at some future date.

Mr. MOORE. Thank you.

Mr. BROWN. The subcommittee will be adjourned.

[Whereupon, at 10:07 a.m., the subcommittee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF
JOHN A. MOORE
ASSISTANT ADMINISTRATOR
FOR PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES

July 28, 1988

Good morning, Mr. Chairman and Members of the Subcommittee. I am pleased to be here to discuss H.R. 4937, the proposed Pesticide Food Safety Act of 1988. This bill consists of three titles. The first amends sections of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pertaining to reregistration and cancellation of pesticide registrations. The second would rewrite the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) that concern pesticide residues in food. The third title would amend the National Agricultural Research, Extension, and Teaching Policy Act of 1985 to establish a new integrated pest management (IPM) initiative.

FIFRA

The goal of Title I of H.R. 4937 is to accelerate the pace of pesticide reregistration under FIFRA. Most people would agree that speeding up reregistration is a desirable goal. However, the bill does not deal at all with the difficult problems that the reregistration process presents--how to get the existing data reviewed, determine what data need to be submitted for each of the hundreds of active ingredients and thousands of end-use products, require its submission, review the new data, require

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all needed labeling changes, and review and change as necessary the Food and Drug Act tolerances associated with the registrations in question. Nor does the bill contain a fee mechanism to provide the large additional sums the Agency will need to accomplish these tasks. In essence, the bill merely requires registrants to apply for reregistration of all currently-registered products by December 1994, and requires EPA to complete its decisions on these applications by the end of 1995. If EPA were to deny an application for reregistration, the registrant would have a right to a denial hearing that can last for up to 18 months--during which time the product remains on the market. Conspicuous by their absence in H.R. 4937 are provisions like those in the other FIFRA amendment bills being considered by Congress that would (1) provide fees to pay for speeding up reregistration and (2) shift to registrants a substantial portion of organizing the data bases that must be reviewed.

Simply setting timeframes and deadlines is not enough. As I have testified before, if the Agency is to be held responsible for completing reregistration within a ten-year period, Congress must give EPA the added necessary additional authority, including the authority for a reregistration fee program. Thus, substantial changes would be required before the Agency could support enactment of Title I of the bill.

FFDCA

Title II of the bill is designed to eliminate two major problems in the current FFDCA. Different standards apply to

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pesticide residues depending on the fortuity of whether the residues are found in raw foods or in processed foods made from those commodities. And section 409's standard for pesticide residues in processed food conflicts with the pesticide registration standard in FIFRA. These problems were discussed in detail in the National Academy of Sciences' 1987 report, "Regulating Pesticides in Food: The Delaney Paradox." That report made two main recommendations: (1) that uniform criteria should be used to regulate all pesticide residues in food, whether the food is raw or processed, and whether the pesticide is new or has been in use for some time; and (2) that for pesticides that may be carcinogens, the principal criterion should be whether the pesticide poses at most a negligible risk to food consumers. The Academy concluded that a negligible risk standard, applied uniformly, could reduce dramatically the total dietary exposure to oncogenic pesticide residues with only modest reduction in benefits. EPA agrees with these conclusions, and appreciates the attention being given to the matter by Congress as shown by this hearing and by proceedings concerning another bill, H.R. 4739, introduced by Congressman Waxman.

H.R. 4937 would adopt the gist of the two NAS recommendations. It would bring all regulation of pesticide residues in food under one set of standards by regulating all pesticide residues under section 408 of the FFDCA. It would regard "negligible risk" as the appropriate standard for establishing legal residue levels in food, while recognizing that there may be

cases where a greater-than-negligible risk may be justified by substantial benefits to consumers. Finally, it would expressly require that new and old tolerances be treated alike. EPA strongly supports these approaches.

However, the bill fails to address a number of other problem areas in the pesticide provisions of the current FFDCA. Section 408 has not been amended appreciably since 1954. Since that time, we have learned a great deal and program needs have changed. In addition, I think it is important to open up the tolerance-setting process to increase public access and input (while avoiding undue delay), and to identify and address specific scientific concerns raised by environmental and consumer organizations. This should increase the public's confidence in the federal pesticide regulatory system and correspondingly decrease the calls for state and local regulation that could disrupt the interstate marketing of food.

To serve these objectives, section 408 should require the publication for comment of informative summaries of petitions for the setting of tolerances or exemptions, and should expressly allow EPA to propose, for public comment, its proposed responses to petitions. Congress could require EPA to request public comment whenever EPA proposes to issue a tolerance that would result in a greater-than-negligible risk, and could limit the term of such a tolerance to require periodic reevaluation. The provision concerning "zero tolerances" in current law should be replaced by straightforward authority for EPA to deny petitions

when appropriate. The law also should provide uniform procedures that would govern the rights and duties of all persons who request EPA to issue, modify, or revoke a tolerance or exemption, and should state clearly the administrative and judicial review rights of all such persons.

Archaic provisions of the 1954 law, such as those concerning the "certification of usefulness" procedure, should be eliminated. Another archaic and unworkable part of the current law is the requirement that EPA respond to a petition with a decision within 90 days. Likewise, a pesticide registrant should not have an automatic right to demand a potentially time-consuming referral to an ad hoc NAS review panel of any proposed EPA action the registrant disagrees with. Although this right has only been exercised once in EPA's history, the potential to delay urgently-needed action is very real.

Importantly, EPA should be authorized to require the submission of data needed to justify the continuation in effect of an existing tolerance or exemption, and should be authorized to revoke a clearance promptly if the required data are not submitted in a timely fashion. In addition, the law should set forth rules for deciding whether food may be lawfully shipped and sold if it contains pesticide residues that were lawful at the time the pesticide was applied but later were the subject of a tolerance revocation action.

Most of the matters I have covered in my last several points would be addressed by Congressman Waxman's bill, H.R. 4739

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(although that bill is problematic in several respects, especially in the highly prescriptive approach it takes to decision-making). Although these issues are not dealt with in H.R. 4937, I think they are all worthy of Congressional attention.

IPM

Title III provides for an IPM initiative which would treat minor use crops that play an important role in the human diet. The Agency is in full agreement with the importance of stressing the value of integrated pest management. I applaud efforts to encourage research and application of methods to make pesticide use more efficient and lower residue levels in food. However, I do not think that Title III should be included in a bill that is primarily intended to modernize the tolerance-setting provisions of the FFDCA. I will defer to the Department of Agriculture for further comments on these provisions.

CONCLUSION

In conclusion, let me say that Title II of H.R. 4937 contains a number of provisions that I support, although there are changes needed that this bill does not address. We will be glad to work with you and other members of Congress on these issues.

PESTICIDE FOOD SAFETY ACT OF 1988

WEDNESDAY, SEPTEMBER 7, 1988

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:35 a.m., in room 1300, Longworth House Office Building, Hon. George E. Brown, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Stenholm, Roberts, Morrison, and Grandy.

Staff present: Glenda L. Temple, clerk; John E. Hogan, minority counsel; William A. Stiles, Jr. and John J. Aguirre.

OPENING STATEMENT OF HON. GEORGE E. BROWN, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. BROWN. The subcommittee will come to order.

I want to thank today's witnesses for returning as we continue our inquiry into the issue of regulating pesticide residues on food and I would like to apologize again to those witnesses who we inconvenienced in our earlier hearing in which we had to suspend due to the urgency of dealing with the drought relief legislation.

The importance of this issue and its complexity is known to all of us on the committee and on the Energy and Commerce Committee, which is also struggling with the regulation of pesticide residues on food.

In holding these hearings, it is my hope that we can improve our knowledge of this issue and be better prepared to effectively legislate our way out of the Delaney paradox, as the National Academy of Sciences study called this policy area.

I look forward to hearing from today's witnesses and can assure them that there should be no reason to postpone today's session any further.

Mr. Roberts, do you have any comments you would like to make at this point?

OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. Yes, Mr. Chairman. I want to thank you for rescheduling this hearing for today and I also want to thank the witnesses and associate myself with your remarks in regard to a personal apology. I know that everybody has a busy schedule and I

regret very much we had to cut short our hearing; however, hopefully that did afford people the opportunity to review the testimony by Dr. Moore, of the EPA.

I have a feeling that everybody here today will tell the subcommittee that the current system of regulating food use pesticides really doesn't work very well. Likewise, we all have very different notions on how to fix the problem. This is a very, very crucial issue for agriculture and obviously for the rest of the country.

You referred to the Delaney Clause as a paradox, Mr. Chairman. I guess in all candor, I don't think it is a very reasonable standard for pesticides and the demands of the statute really don't marry up very well with the FIFRA Act. These conflicts between these two statutes really result in what I call regulatory gridlock and it weighs very heavily on the EPA and the proper administration of that policy.

This does equate, I think, to lost consumer confidence and the American farmer suffers as a direct result. So I see the subcommittee is very uniquely positioned to really try to address these issues and I look forward to the testimony of the witnesses who are here today.

Mr. BROWN. Any other committee members have any statements to make?

[No response.]

Mr. BROWN. In that case, we then will welcome Dr. Charles Benbrook, the executive director of the board of agriculture, National Academy of Sciences, and the former distinguished staff director of this subcommittee.

You may proceed with your testimony, Dr. Benbrook.

**STATEMENT OF CHARLES M. BENBROOK, EXECUTIVE DIRECTOR,
BOARD OF AGRICULTURE, NATIONAL ACADEMY OF SCIENCES**

Mr. BENBROOK. Thank you, Mr. Chairman, Mr. Roberts, members of the subcommittee, it is a pleasure to be here. It has been a long time since I sat up there and watched what goes on down here. I will try to act on some of the lessons I learned in my earlier role on the subcommittee's staff.

I have a written statement that I would ask to be included in the record, and I will merely summarize a few points.

Mr. BROWN. Without objection, it will be fully entered.

Mr. BENBROOK. Mr. Roberts, you are right, the regulatory program addressing pesticides is subject to a sort of chronic gridlock and one of the most difficult issues that gives rise to this gridlock deals with what regulatory action should be taken on a set of older pesticides that have been shown to cause cancer in laboratory animals.

This problem that EPA faces dealing with several dozen older pesticides really was what led the agency 4 years ago to seek the help of the National Academy of Sciences. We were asked to study this problem and come up with some recommendations on ways to perhaps resolve or unravel the basic fundamentals that give rise to this gridlock.

Four years later, and a lot of hard work and a lot of additional data having flowed under the bridge, I can't say that there is any

real reason for hope. The system is no simpler; the scientific issues are no more clear-cut; the political decisions are no easier. I would urge this subcommittee, as just a general notion, to be very wary of legislative changes now that add substantial complexity to the program. The regulatory program is very complex already. It is outstripping the resources of the agency to implement it; it is outstripping the economic capacity of registrants to pay for the science and the legal work that has to be done to deal with the regulatory requirements and it is outstripping the ability of the farmer to pay for the crop-protection chemicals.

You really have to start asking yourself, is this system worth it and do we really want to continue in the direction we are going? Is there enough public interest at stake?

Another general point I want to make—it is a matter of great confusion amongst people—involves the circumstances that give rise to the concentration of a pesticide in processed foods.

As you remember, the Delaney Clause problem in pesticide regulation arises when a pesticide residue concentrates in a processed food to a level above that which appears in the raw food, or the fresh food product. This fact of concentration triggers the need for a tolerance to be established under section 409 of the Food, Drug and Cosmetic Act, a part of which is the so-called Delaney Clause.

So the issue of concentration as a legal matter is key to the problem that gave rise to the National Academy study, and the problem addressed in the Roberts-Brown bill.

Now, a lot of people will come up here and say that pesticides rarely concentrate. They will cite thousands of tests that have been run which never or rarely find instances where pesticides concentrate. It is very important for you to understand basically when pesticides do concentrate.

If you have a pesticide that appears on food, on the external surface where it is washed off, either by the consumer or in processing, then it will rarely concentrate. If it is a pesticide that biologically degrades in the presence of air in the environment soon after it is sprayed, it will rarely concentrate. But there are a number of pesticides that are systemic or which become embedded in the fruit, or meat of a vegetable or other foodstuff, and whenever you take some of that food and process it into other products that involve breaking it into component parts, that is where you have a high likelihood of concentration in at least one of those component parts.

When you take corn and turn it into corn oil; or other crops and turn them into oil, oftentimes whatever pesticides are in the residues or on the soybean or in the corn kernel, they will either concentrate in the oil or in the mash that is left after the crushing of grain into oil. Whenever you dry fruit or vegetables—which simply involves taking water and hence weight out—you will have a higher concentration of any pesticide residues by weight in the dried product.

So there are certain circumstances where you are going to get concentration fairly regularly, and other circumstances when you almost never will. It is important to recognize the difference.

As a regulatory matter, as long as for a few processed products made from corn or citrus or soybean or wheat, as long as a

products are subject to this phenomenon of concentration, from EPA's point of view, that triggers the whole set of regulatory considerations that are dealt with in the Roberts-Brown bill.

So it is true that concentration above published tolerance levels rarely occur, but it is also true that as a regulatory matter, it occurs enough that it is a major problem.

Speaking to the Roberts-Brown bill that is before the subcommittee, I believe that this bill reflects as simple and literal a translation of the recommendations of the National Academy into legislation as is possible. I believe in crafting the bill, Congressman Roberts, you sought to develop a bill that simply and cleanly deals with the fundamental recommendations in the Academy report and I think that it does that pretty well.

It eliminates the inconsistency in the standard between raw and processed food by applying basically the same negligible-risk standard to residues in both raw and processed foods. It calls for a consistent negligible-risk standard to be applied to both, and it deals with the fundamental issue of inconsistent standards being applied to old and new pesticides by proposing an important change in the reregistration process.

I would like to speak to that issue because, fundamentally, the problem with reregistration, the problem that EPA has in regulating older pesticides, stems from two or three dozen older pesticides that are still very valuable tools to farmers but happen to also pose potentially substantial risks to either man or the environment. So it is this pool of older products that keeps coming up over and over again that really is the problem. Until EPA can work through them in the reregistration process and come up with ways that those products can be used in accordance with contemporary standards, this issue will not go away.

In the context of reregistration and in the context of having the same negligible-risk standard apply to new or old pesticides, the Roberts-Brown bill proposes that the act of reregistering a pesticide become essentially the same, or in the words of the bill, the "functional equivalent of an initial registration."

Now, some people believe that this marks no change from the current statute, but let me assure you it certainly does in practice. Today, for EPA to suspend or cancel a pesticide, it has to have sufficient data and scientific information to prove that a substantial risk is faced, either by man, by a farmer or applicator of the pesticide, or to wildlife. This proves to be often a very difficult scientific task, so a pesticide basically remains on the market and in use until there is a substantial body of evidence that there is considerable harm being done.

This is really a very serious problem because it places a scientific burden on the agency that it can only handle in one or two or three regulatory cases each year. So the idea behind turning reregistration into basically the same process as registration, following a longer period of time, is to give the agency an opportunity for a clean review of a pesticide, based on current standards and currently registered products. The question the agency would face is whether an older pesticide basically cuts the butter in terms of the balance of risks and benefits that it poses.

Analytically and technically, this is an important difference because in this case, EPA evaluates the risk of a pesticide in contrast to other registered alternatives. It is often much easier for EPA to say that pesticide X is safer than pesticide Y. It may have a much more difficult time, however, predicting with any degree of certainty the absolute risk associated with either, but at least it can make a judgment that one is safer than the other. If the risks from one pesticide are substantially greater than another which offers about equal benefits, under the Roberts-Brown reregistration process the agency would be expected to leave on the market the safer pesticide and not reregister the one that is proven to pose greater risk but not significantly greater benefits.

Now, given that there are many products registered for most major uses of pesticides, and sometimes several products from a similar chemical class, it is very likely that EPA is going to find itself forced to evaluate the relative risks and benefits for 6, 8, 10, even more products that are, say, herbicides for corn or soybeans. It is going to prove, I think, a lot easier for the agency to determine, say, the 4 safest out of a set of 6 pesticides, or the 2 most risky out of a set of 10, and take appropriate regulatory action on those than it will be to come up with an absolute certainty of what the risks are for each one of those compared to some absolute standard.

So this is the concept behind this new approach to reregistration and I believe it would greatly facilitate the task that EPA faces when it comes up to major groups of products about which they really are not sure which is the most risky or the least risky or how to proceed.

The legislation also has, I think, an important title which would move along the process of developing some integrated pest-management systems. I think that it is likely that the subcommittee will return to those issues as it begins to craft the research title of the next farm bill, but I would be glad to answer any questions on that title.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Benbrook appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Dr. Benbrook.

Mr. Roberts.

Mr. ROBERTS. Yes, thank you, Mr. Chairman.

I would just like to state from a few paragraphs of a previous statement when we had the hearing before when I stated, in the eyes of our farm organizations, and more especially, the farmers and ranchers of this country, nothing is more important than the confidence of the consumer in the safety of our food supply. I know I speak for many of my colleagues that, as a farm State Member of this Congress, no prospect worries me more than the notion or a real fear of pesticide residues would or could cause a real choice and a real frustration and a real fear on the part of the consumer as they try to purchase the kinds of foods that we purchase in this country at the grocery store.

We are very proud of what we think is the best quality food in the history of the world at the lowest possible price and in that respect, I think agriculture has been, what, maybe hunkering d

in the weeds too much in a defensive posture. We have to accept this challenge. We have to become much more, I think, aggressive in embracing what you referred to as an end to the complexity of the problem and the regulatory gridlock.

I want the subcommittee to know, and I want all present to know, that the NAS report, which you are largely responsible for, is indeed a watershed study. It is a blueprint for change, if you will, in the processes and the policies that do govern the pesticide residue.

We in the Ag Committee should embrace the report; we should encourage the elevation of safety standards to the rational and consistent regulation of pesticide residues. Now, that is a tall order and I notice that you had on your dark hat this morning in terms of doom and gloom. I still remain, I guess, an eternal optimist, but I want to pay a large amount of personal credit to Dr. Benbrook, Mr. Chairman, for his efforts in this regard and if we are to achieve success, and we must, it will be in large part to the efforts of very dedicated folks like yourself.

So in behalf of the farmers and ranchers in my district and in Kansas, I want to thank you for your efforts.

Now, since apparently that caused the TV lights to go off with all of that milk of human kindness, let me ask just a couple of questions.

You know that we received some criticism in regard to the Roberts-Brown bill, H.R. 4937, that this bill is too loose; that we need greater elaboration similar to the bill that has been introduced by our friend and colleague, Mr. Waxman, H.R. 4739. On page 5, that you did not read, in the first paragraph, you have indicated: "There is now widespread agreement that both exposure and potential risk is heavily concentrated in relatively few foods following the use of perhaps a dozen pesticides."

If this is so, do you believe that the approach used by the bill introduced by the chairman and myself or the Waxman bill would achieve the greatest risk reduction, because that is what we want, and in terms of cost, and most important, I want real progress. I don't want an issue; I don't want to debate it anymore, and so in terms of minimal disruption to agriculture in the shortest period of time to get some progress, which approach do you think would be best?

Mr. BENBROOK. First of all, Mr. Roberts, under FIFRA and any subsequent legislation affecting FIFRA, for it to bring about any real risk reduction, it is going to require leadership from EPA and some determination to bring that about. Laws alone can't do it.

But to answer your question directly, risk could be reduced much more quickly under the Roberts-Brown bill. It is less prescriptive; it is more flexible and, as a result, it can be enacted, or acted upon much more quickly.

The Waxman bill, on the other hand, is fairly complicated both technically and procedurally. It requires many things to happen, and establishes a precise set of rules and process, which will themselves require much effort to fully specify and implement, until this is done, probably no regulatory action or real risk reduction would be brought about until the various procedures had been car-

ried out fully in accordance with the new provisions in that statute.

So I think that if somebody wanted to go in and identify the highest risk uses of pesticides, and take actions to reduce risk, they could do so most quickly and expeditiously under the Roberts-Brown bill.

Mr. ROBERTS. Want to and can do are two different things. We are going to hear from some witnesses on down the road here that simply do not trust the EPA to do that job and I would say that mistrust would be regardless of who has that responsibility. On one hand, if you really dot the I and you cross the T and you come with some very rigid guidelines and definitions, I think you can make the argument that, by golly, this is what you are going to do, now do it. On the other side of it, if you do it that way, you may cause a tremendous cost and disruption to agriculture that may or may not have a bearing on the safety issue and I would like to see some progress.

I would like to see at least some degree of flexibility so that the EPA Administrator will not step into a hornet's nest every time he makes a decision. We have had enough of that. We have had enough of this adversity. That is the point I am trying to make.

My time is expired, Mr. Chairman. I think I will yield back at this point, but I do have two other questions for Dr. Benbrook at a later point.

Mr. BROWN. We will get back to you.

Mr. Stenholm.

Mr. STENHOLM. Dr. Benbrook, some suggest that we don't have leadership within EPA. I have, for a long time, wondered how we get leadership from any of the administrative offices of our government when we continue to have such diversity of opinion among those who are asking for the leadership. It is almost impossible, I believe, for anyone to give leadership when there is not an agreement on what action needs to be taken.

For example, I am told that there are studies that show that if we eliminate all pesticides from the face of the earth that there would still be 99 percent of the known carcinogens still present in the world. Is that a reasonable statement?

Mr. BENBROOK. I think it is sufficiently hypothetical to not be very relevant to the current debate. There are a lot of things that cause cancer. Some of them are natural and some of them are man-made. There is the beginning of some very interesting work to try to understand the relative degree of risks that are imposed by man-made and natural carcinogens, but I don't think that we know quite enough yet to say with certainty that 99 percent of the carcinogens are natural or man-made or whatever, but it is an important area to try to get a better handle on because we just might be missing the boat fairly substantially with our current set of policies.

It has raised an important question, but I don't think that the science is so clear that it would support a major change in regulatory policy. That is my opinion.

Mr. STENHOLM. You, in your testimony, lean toward supporting the bill that we are considering today. It appears that you support the establishing of tolerance levels for various pesticides rather

than having an absolute ban based on an ability to measure the presence of various carcinogens? Is that correct?

Mr. BENBROOK. That is right, and the idea being that it is now possible, at least regulatory agencies are doing it fairly regularly, to define a level of exposure for toxic chemicals below which there really is no prudent basis for great concern about there being a health hazard. I think that that can be done now in the case of most pesticide residues in food and the point of the NAS Delaney report is that the vast majority of pesticide uses under current farming practices are going to result in a residue well below that level. The vast majority.

There is already sufficient information in the files of EPA to identify most of those uses that are clearly above that level. But instead of contemplating 600 active ingredients and some 15,000 food uses of pesticides that aren't going to be fully reregistered until the year 2050, assuming Congress appropriates sufficient funds and doesn't change the law six times in between, instead of this enormous task, the problem becomes manageable by focusing on just these uses that may pose greater than negligible risk.

If you take the current uses of pesticides and say, "Which ones pose a risk that is possibly above a negligible level," you go from tens of thousands of uses of individual pesticides down to just a few hundred. Then you can begin to deal with those.

When you find a use of a pesticide that appears that it may pose risks above the negligible level, you ask yourself, "Is the data that suggests such risk valid, is that data scientifically sound? Are the residues really there?" That is the first thing you ask. We can do a better job of doing exposure assessments from pesticides in the diet so we look at the data and say, "Are the real residues there?" Oftentimes, they are not. There are many orders of magnitude less than what the published tolerance level is.

Just by a simple analysis of the exposure, one soon loses that concern. But in some instances, there will still be a concern. Then you have to say, "Is there a way we can use the pesticide to reduce the level in the foods," and oftentimes there are. You can use it in a different way, a different formulation, but after you go through all the steps, there is still going to be some uses that pose greater than negligible risk, and it is those uses that should be acted upon in an expeditious way.

If the regulatory agency can get to the point where it can convince the public and the Congress that it is routinely identifying these potentially risky uses, and as a result reducing risk without a lot of hand-waving, then there is going to be some confidence restored in this whole process. But right now, because nothing is happening on any front, the public gets the impression that all pesticides must be equally bad. It is just as bad to eat Mr. Roberts' wheat as your constituents' cattle and Mr. Brown's citrus.

But it is just not that way. That is the point of the Academy report, that there is a way to proceed where we can identify the worse risks and take whatever steps are necessary to do something about it. It is a relatively small proportion of all uses of pesticides, a very small proportion of the total pesticides used in American agriculture.

That is my speech.

Mr. STENHOLM. I appreciate your answer.

Mr. BROWN. Dr. Benbrook, the point that is raised here about the relative burden of carcinogenic elements represented by pesticides, even though there is probably not an adequate scientific basis for it, is an interesting question, as you have indicated, and it would be, I think, helpful for our record if there were any published material that indicates what this relative burden from pesticides might be.

Of course, this opens up the whole question of other routes of exposure to humans of carcinogens and these come through the air, through any number of different things, both natural and man-made sources. If there is available anything that would throw any light on this subject that you know of, I would appreciate your making that available to the subcommittee.

Mr. BENBROOK. Mr. Chairman, Dr. Bruce Ames, who is a distinguished microbiologist and member of the National Academy, has really pioneered this whole concept of trying to develop a ranking system for man-made versus natural carcinogens. In the wake of all the press attention our report engendered when we released it, Dr. Ames and I engaged in a quite interesting dialogue through the mail. I have all of his pertinent articles. I would be glad to submit a package of materials for the record.

[The information follows:]

NATIONAL RESEARCH COUNCIL

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BOARD ON AGRICULTURE

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October 5, 1988

Honorable George E. Brown, Jr.
Chairman
House Subcommittee on Department
Operations, Research, & Foreign Agriculture
2256 Rayburn House Office Building
Washington, D.C. 20515-0536

Dear Mr. Chairman:

I appreciated the opportunity to testify before the subcommittee September 7 on the Roberts-Brown food safety bill.

Please find enclosed material in response to your questions regarding cancer risks from exposure to natural and manmade substances: the most recent article in Science by Dr. Bruce Ames describing his relative risk ranking scheme, and correspondence with Dr. Ames exploring some of the interesting analytical challenges that must be overcome to develop a more refined analysis. I agree fully with you that Dr. Ames research raises significant questions, both in evaluating pesticide regulatory policy, and in considering how certain applications of biotechnology in plant variety development should be evaluated, or even possibly regulated.

As you know, a very different body of law, regulations, legal precedents, and public attitudes address natural constituents of food, in contrast to manmade chemicals (pesticide, animal drug, or food additive residues). Since the goal of all such laws is public health promotion, a re-evaluation of these policies seems warranted to assure that a proper balance is being struck in our regulatory programs. A part of such an analysis should be a more sophisticated and complete empirical assessment of the nature and level of risks from manmade and natural chemicals in food. I would urge DORFA to pursue how such a study could be undertaken.

I also enclose information in response to Mr. Stenholm's questions regarding cancer trends. Please find the Executive Summary of the most recent NCI Atlas of Cancer, a review article of epidemiological studies on cancer risks faced by farmers, and a just published report on a new epidemiological study done in Italy.

There is a growing body of evidence regarding the presence of nitrates and triazine herbicide residues in drinking water in major farming regions. These chemicals can react in the stomach to form nitrosamine compounds, many of which are known to be potent carcinogens. Until recently, the principal route of exposure, and concern among farmers relative to pesticide risks stemmed from occupational exposures. It is now extremely

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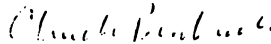
Congressman George E. Brown, Jr.
 October 5, 1988
 Page 2

important, I believe, to evaluate the potential risks to farm families and rural communities from water-based exposures. Again, I would urge DORFA to consider holding a hearing, or undertaking other information generating activities to explore the adequacy of ongoing research designed to determine the magnitude of farm-related toxic hazards.

I would like to offer congratulations to you and the subcommittee upon the final passage of the FIFRA. After so many years of effort, it must be a considerable relief. Without doubt, the bill will help a great deal in resolving some of the major problems in the registration process.

Again, thanks for the opportunity to appear before the subcommittee.

Sincerely,



Charles M. Benbrook
 Executive Director

Enclosures

c: Skip Stiles w/enclosures

Ranking Possible Carcinogenic Hazards

BRUCE N. AMES,* RENAE MAGAW, LOIS SWIRSKY GOLD

This review discusses reasons why animal cancer tests cannot be used to predict absolute human risks. Such tests, however, may be used to indicate that some chemicals might be of greater concern than others. Possible hazards to humans from a variety of rodent carcinogens are ranked by an index that relates the potency of each carcinogen in rodents to the exposure in humans. This ranking suggests that carcinogenic hazards from current levels of pesticide residues or water pollution are likely to be of minimal concern relative to the background levels of natural substances, though one cannot say whether these natural exposures are likely to be of major or minor importance.

EPIDEMIOLOGISTS ESTIMATE THAT AT LEAST 70% OF HUMAN cancer would, in principle, be preventable if the main risk and antirisk factors could be identified (1). This is because the incidence of specific types of cancer differs markedly in different parts of the world where people have different life-styles. For example, colon and breast cancer, which are among the major types of cancer in the United States, are quite rare among Japanese in Japan, but not among Japanese-Americans. Epidemiologists are providing important clues about the specific causes of human cancer, despite inherent methodological difficulties. They have identified tobacco as an avoidable cause of about 30% of all U.S. cancer deaths and of an even larger number of deaths from other causes (1, 2). Less specifically, dietary factors, or their absence, have been suggested in many studies to contribute to a substantial proportion of cancer deaths, though the intertwined risk and antirisk factors are being identified only slowly (1, 3, 4). High fat intake may be a major contributor to colon cancer, though the evidence is not as definitive as that for the role of saturated fat in heart disease or of tobacco in lung cancer. Alcoholic beverage consumption, particularly by smokers, has been estimated to contribute to about 3% of U.S. cancer deaths (1) and to an even larger number of deaths from other causes. Progress in prevention has been made for some occupational factors, such as asbestos, to which workers used to be heavily exposed, with delayed effects that still contribute to about 2% of U.S. cancer deaths (1, 5). Prevention may also become possible for hormone-related cancers such as breast cancer (1, 6), or virus-related cancers such as liver cancer (hepatitis B) and cancer of the cervix (papilloma virus HPV16) (1, 7).

Animal bioassays and *in vitro* studies are also providing clues as to which carcinogens and mutagens might be contributing to human cancer. However, the evaluation of carcinogenicity in rodents is expensive and the extrapolation to humans is difficult (8-11). We will use the term "possible hazard" for estimates based on rodent cancer tests and "risk" for those based on human cancer data (10).

Extrapolation from the results of rodent cancer tests done at high

does to effects on humans exposed to low doses is routinely attempted by regulatory agencies when formulating policies attempting to prevent future cancer. There is little sound scientific basis for this type of extrapolation, in part due to our lack of knowledge about mechanisms of cancer induction, and it is viewed with great unease by many epidemiologists and toxicologists (5, 9-11). Nevertheless, to be prudent in regulatory policy, and in the absence of good human data (almost always the case), some reliance on animal cancer tests is unavoidable. The best use of them should be made even though few, if any, of the main avoidable causes of human cancer have typically been the types of man-made chemicals that are being tested in animals (10). Human cancer may, in part, involve agents such as hepatitis B virus, which causes chronic inflammation; changes in hormonal status; deficiencies in normal protective factors (such as selenium or β -carotene) against endogenous carcinogens (12); lack of other anticarcinogens (such as dietary fiber or calcium) (4); or dietary imbalances such as excess consumption of fat (3, 4, 12) or salt (13).

There is a need for more balance in animal cancer testing to emphasize the foregoing factors and natural chemicals as well as synthetic chemicals (12). There is increasing evidence that our normal diet contains many rodent carcinogens, all perfectly natural or traditional (for example, from the cooking of food) (12), and that no human diet can be entirely free of mutagens or agents that can be carcinogenic in rodent systems. [We need to identify the important causes of human cancer among the vast number of minimal risks. This requires knowledge of both the amounts of a substance to which humans are exposed and its carcinogenic potency.]

Animal cancer tests can be analyzed quantitatively to give an estimate of the relative carcinogenic potencies of the chemicals tested. We have previously published our Carcinogenic Potency Database, which showed that rodent carcinogens vary in potency by more than 10 millionfold (14).

This article attempts to achieve some perspective on the plethora of possible hazards to humans from exposure to known rodent carcinogens by establishing a scale of the possible hazards for the amounts of various common carcinogens to which humans might be chronically exposed. We view the value of our calculations not as providing a basis for absolute human risk assessment, but as a guide to priority setting. One problem with this type of analysis is that few of the many natural chemicals we are exposed to in very large amounts (relative to synthetic chemicals) have been tested in animals for carcinogenicity. Thus, our knowledge of the background levels of human exposure to animal carcinogens is fragmentary, biased in favor of synthetic chemicals, and limited by our lack of knowledge of human exposures.

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*To whom reprint requests should be sent.

virus (19, 20). Considering the potency of those mold toxins that have been tested and the widespread contamination of food with molds, they may represent the most significant carcinogenic pollution of the food supply in developing countries. Such pollution is much less severe in industrialized countries, due to refrigeration and

modern techniques of agriculture and storage, including use of synthetic pesticides and fumigants.

Preparation of foods and beverages can also produce carcinogens. Alcohol has been shown to be a human carcinogen in numerous epidemiologic studies (1, 21). Both alcohol and acetaldehyde, as

Table 1. Ranking possible carcinogenic hazards. Potency of carcinogens: A number in parentheses indicates a TD_{50} value not used in HERP calculation because it is the less sensitive species; (-) = negative in cancer test; (+) = positive for carcinogenicity in test(s) not suitable for calculating a TD_{50} ; (?) = is not adequately tested for carcinogenicity. TD_{50} values shown are averages calculated by taking the harmonic mean of the TD_{50} 's of the positive tests in that species from the Carcinogenic Potency Database. Results are similar if the lowest TD_{50} value (most potent) is used instead. For each test the target site with the lowest TD_{50} value has been used. The average TD_{50} has been calculated separately for rats and mice, and the more sensitive species is used for calculating the possible hazard. The database, with references to the source of the cancer tests, is complete for tests published through 1984 and for the National Toxicology Program bioassays through June 1986 (14). We have not indicated the route of exposure or target sites or other particulars of each test, although these are reported in the database. *Daily human exposure:* We have tried to use average or reasonable daily intakes to facilitate comparisons. In several cases, such as contaminated well water or factory exposure to EDB, this is difficult to determine, and we give the value for the worst found and indicate pertinent information in the References and Notes. The calculations assume a daily dose for a lifetime; where drugs are normally taken for only a short period we have bracketed the HERP value. For inhalation exposures we assume an inhalation of 9,600 liters per 8 hours for the workplace and 10,800 liters per 14 hours for indoor air at home. *Possible hazard:* The amount of rodent carcinogen indicated under carcinogen dose is divided by 70 kg to give a milligram per kilogram of human exposure, and this human dose is given as the percentage of the TD_{50} dose in the rodent (in milligrams per kilogram) to calculate the Human Exposure Rodent Potency index (HERP).

Possible hazard HERP (%)	Daily human exposure	Carcinogen dose per 70-kg person	Potency of carcinogen: TD ₅₀ (mg/kg)		References
			Rats	Mice	
Environmental pollution					
0.001*	Tap water, 1 liter	Chloroform, 83 µg (U.S. average)	(119)	90	96
0.004*	Well water, 1 liter contaminated (worst well in Silicon Valley)	Trichloroethylene, 2800 µg	(-)	941	97
0.0004*	Well water, 1 liter contaminated, Woburn	Trichloroethylene, 267 µg	(-)	941	98
0.0002*		Chloroform, 12 µg	(119)	90	
0.0003*		Tetrachloroethylene, 21 µg	101	(126)	
0.008*	Swimming pool, 1 hour (for child)	Chloroform, 350 µg (average pool)	(119)	90	99
0.6	Conventional home air (14 hour day)	Formaldehyde, 596 µg	1.5	(44)	100
0.004		Benzene, 155 µg	(157)	53	
2.1	Mobile home air (14 hour/day)	Formaldehyde, 2.2 mg	1.5	(44)	28
Pesticide and other residues					
0.0002*	PCBs: daily dietary intake	PCBs, 0.2 µg (U.S. average)	1.7	(9.6)	101
0.0003*	DDE/DDT: daily dietary intake	DDE, 2.2 µg (U.S. average)	(-)	13	16
0.0004	EDB: daily dietary intake (from grains and grain products)	Ethylene dibromide, 0.42 µg (U.S. average)	1.5	(5.1)	102
Natural pesticides and dietary toxins					
0.003	Bacon, cooked (100 g)	Dimethylnitrosamine, 0.3 µg	(0.2)	0.2	40
0.006		Diethylnitrosamine, 0.1 µg	0.02	(-)	
0.003	Sake (250 ml)	Urethane, 43 µg	(41)	22	24
0.03	Comfrey herb tea, 1 cup	Symphytine, 38 µg (750 µg of pyrrolizidine alkaloids)	1.9	(?)	103
0.03	Peanut butter (32 g; one sandwich)	Aflatoxin, 64 ng (U.S. average, 2 ppb)	0.003	(-)	18
0.06	Dried squid, broiled in gas oven (54 g)	Dimethylnitrosamine, 7.9 µg	(0.2)	0.2	3*
0.07*	Brown mustard (5 g)	Allyl isothiocyanate, 4.6 mg	96	(-)	4*
0.1	Basil (1 g of dried leaf)	Estragole, 3.8 mg	(?)	52	48
0.1	Mushroom, one raw (15 g) (<i>Agaricus bisporus</i>)	Mixture of hydrazines, and so forth	(?)	20,300	104
0.2	Natural root beer (12 ounces, 354 ml) (now banned)	Safrole, 6.6 mg	(436)	56	105
0.008	Beer, before 1979 (12 ounces, 354 ml)	Dimethylnitrosamine, 1 µg	(0.2)	0.2	38
2.8*	Beer (12 ounces, 354 ml)	Ethyl alcohol, 18 ml	9110	(?)	23
4.7*	Wine (250 ml)	Ethyl alcohol, 30 ml	9110	(?)	23
0.2	Comfrey-peppan tablets (nine daily)	Comfrey root, 2700 mg	626	(?)	103
1.3	Comfrey-peppan tablets (nine daily)	Symphytine, 1.8 mg	1.9	(?)	
Food additives					
0.0002	AF-2: daily dietary intake before banning	AF-2 (furfurylamide), 4.8 µg	29	(131)	44
0.06*	Diet Cola (12 ounces, 354 ml)	Saccharin, 95 mg	2143	(-)	106
Drugs					
0.3	Phenacetin pill (average dose)	Phenacetin, 300 mg	1246	(2137)	51
5.6	Metronidazole (therapeutic dose)	Metronidazole, 2000 mg	(542)	506	107
14	Isoniazid pill (prophylactic dose)	Isoniazid, 300 mg	(150)	30	108
16*	Phenobarbital, one sleeping pill	Phenobarbital, 60 mg	(+)	5.5	50
1.7*	Clofibrate (average daily dose)	Clofibrate, 2000 mg	169	(?)	52
Occupational exposure					
5.8	Formaldehyde: Workers' average daily intake	Formaldehyde, 6.1 mg	1.5	(44)	109
140	EDB: Workers' daily intake (high exposure)	Ethylene dibromide, 150 mg	1.5	(5.1)	55

* Asterisks indicate HERP from carcinogens thought to be nongenotoxic.

received by today's uranium miners. Two particularly contaminated houses were found that had a risk estimated to be equivalent to receiving about 1200 chest x-rays a day (49). Approximately 10% of the lung cancer in the United States has been tentatively attributed to radon pollution in houses (49). Many of these cancers might be preventable since the most hazardous houses can be identified and modified to minimize radon contamination.

General outdoor air pollution appears to be a small risk relative to the pollution inhaled by a smoker: one must breathe Los Angeles smog for a year to inhale the same amount of burnt material that a smoker (two packs) inhales in a day (12), though air pollution is inhaled starting from birth. It is difficult to determine cancer risk from outdoor air pollution since epidemiologists must accurately control for smoking and radon.

Some common drugs shown in Table 1 give fairly high HERP percentages, primarily because the dose ingested is high. However, since most medicinal drugs are used for only short periods while the HERP index is a daily dose rate for a lifetime, the possible hazard would usually be markedly less. We emphasize this in Table 1 by bracketing the numbers for these shorter exposures. Phenobarbital (HERP = 16%) was investigated thoroughly in humans who had taken it for decades, and there was no convincing evidence that it caused cancer (50). There is evidence of increased renal cancer in long-term human ingestion of phenacetin, an analgesic (51). Acetaminophen, a metabolite of phenacetin, is one of the most widely used over-the-counter pain killers. Clofibrate (HERP = 17%) is used as a hypolipidemic agent and is thought to be carcinogenic in rodents because it induces hydrogen peroxide production through peroxisome proliferation (52).

Occupational exposures can be remarkably high, particularly for volatile carcinogens, because about 10,000 liters of air are inhaled in a working day. For formaldehyde, the exposure to an average worker (HERP = 5.8%) is higher than most dietary intakes. For a number of volatile industrial carcinogens, the ratio of the permitted exposure limit [U.S. Occupational Safety and Health Administration (OSHA)] in milligrams per kilogram to the TD_{50} has been calculated; several are close to the TD_{50} in rodents and about two-thirds have permitted HERP values >1% (53). The possible hazard estimated for the actual exposure levels of the most heavily exposed EDB workers is remarkably high, HERP = 140% (Table 1). Though the dose may have been somewhat overestimated (54), it was still comparable to the dose causing cancer in half the rodents. An epidemiologic study of these heavily exposed EDB workers who inhaled EDB for over a decade did not show any increase in cancer, though because of the limited duration of exposure and the relatively small numbers of people monitored the study would not have detected a small effect (54, 55). OSHA still permits exposures above the TD_{50} level. California, however, lowered the permitted level over 100-fold in 1981. In contrast with these heavy workplace exposures, the Environmental Protection Agency (EPA) has banned the use of EDB for fumigation because of the residue levels found in grain (HERP = 0.0004%).

Uncertainties in Relying on Animal Cancer Tests for Human Prediction

Species variation. Though we list a possible hazard if a chemical is a carcinogen in a rat but not in a mouse (or vice versa), this lack of agreement raises the possibility that the risk to humans is nonexistent. Of 392 chemicals in our database tested in both rats and mice, 226 were carcinogens in at least one test, but 96 of these were positive in the mouse and negative in the rat or vice versa (56). This discordance occurs despite the fact that rats and mice are very closely

related and have short life-spans. Qualitative extrapolation of cancer risks from rats or mice to humans, a very dissimilar long-lived species, is unlikely to be as reliable. Conversely, important human carcinogens may not be detected in standard tests in rodents; this was true for a long time for both tobacco smoke and alcohol, the two largest identified causes of neoplastic death in the United States.

For many of the chemicals considered rodent carcinogens, there may be negative as well as positive tests. It is difficult to deal with negative results satisfactorily for several reasons, including the fact that some chemicals are tested only once or twice, while others are tested many times. The HERP index ignores negative tests. Where there is species variation in potency, use of the more sensitive species, as is generally done and as is done here, could introduce a tendency to overestimate possible hazards; however, for most chemicals that are positive in both species, the potency is similar in rats and mice (57). The HERP may provide a rough correlate of human hazard from chemical exposure; however, for a given chemical, to the extent that the potency in humans differs from the potency in rodents, the relative hazard would be different.

Quantitative uncertainties. Quantitative extrapolation from rodents to humans, particularly at low doses, is guesswork that we have no way of validating (1, 5, 10, 11, 58). It is guesswork because of lack of knowledge in at least six major areas: (i) the basic mechanisms of carcinogenicity; (ii) the relation of cancer, aging, and life-span (1, 10, 42, 59); (iii) the timing and order of the steps in the carcinogenic process that are being accelerated; (iv) species differences in metabolism and pharmacokinetics; (v) species differences in anticarcinogens and other defenses (1, 60); and (vi) human heterogeneity—for example, pigmentation affects susceptibility to skin cancer from ultraviolet light. These sources of uncertainty are numerous, and so substantial, that only empirical data will resolve them, and little of this is available.

Uncertainties due to mechanism in multistage carcinogenesis. Several steps (stages) are involved in chemical carcinogenesis, and the dose-response curve for a carcinogen might depend on the particular stage(s) it accelerates (58), with multiplicative effects if several stages are affected. This multiplicative effect is consistent with the observation in human cancer that synergistic effects are common. The three steps of carcinogenesis that have been analyzed in most detail are initiation (mutation), promotion, and progression, and we discuss these as an aid to understanding aspects of the dose-response relation.

Mutation (or DNA damage) as one stage of the carcinogenic process is supported by various lines of evidence: association of active forms of carcinogens with mutagens (61), the changes in DNA sequence of oncogenes (62), genetic predisposition to cancer in human diseases such as retinoblastoma (63) or DNA-repair deficiency diseases such as xeroderma pigmentosum (64). The idea that genotoxic carcinogens might show a linear dose-response might be plausible if only the mutation step of carcinogenesis was accelerated and if the induction of repair and defense enzymes were not significant factors (65).

Promotion, another step in carcinogenesis, appears to involve cell proliferation, or perhaps particular types of cell proliferation (66), and dose-response relations with apparent thresholds, as indicated by various lines of evidence: (i) The work of Trosko *et al.* (67) on promotion of carcinogenesis due to interference with cell-cell communication, causing cell proliferation. (ii) Rajewsky's and others work indicating initiation by some carcinogenic agents appears to require proliferating target cells (68). (iii) The work of Farber *et al.* (69) on liver carcinogenesis supports the idea that cell proliferation (caused by partial hepatectomy or cell killing) can be an important aspect of hepatocarcinogenesis. They have also shown for several chemicals that hepatic cell killing shows a toxic threshold with dose. (iv) Work on carcinogenesis in the pancreas, bladder and stomach

lack the knowledge to do low-dose "risk assessment." We also are almost completely ignorant of the carcinogenic potential of the enormous background of natural chemicals in the world. For example, cholinesterase inhibitors are a common class of pesticides, both man-made and natural. Solanine and chaconine (the main alkaloids in potatoes) are cholinesterase inhibitors and were introduced generally into the human diet about 400 years ago with the dissemination of the potato from the Andes. They can be detected in the blood of almost all people (12, 90). Total alkaloids are present at a level of 15,000 µg per 200-g potato with not a large safety factor (about sixfold) from the toxic level for humans (91). Neither alkaloid has been tested for carcinogenicity. By contrast, malathion, the main synthetic organophosphate cholinesterase inhibitor in our diet (17 µg/day) (16), is not a carcinogen in rodents.

The idea that nature is benign and that evolution has allowed us to cope perfectly with the toxic chemicals in the natural world is not compelling for several reasons: (i) there is no reason to think that natural selection should eliminate the hazard of carcinogenicity of a plant toxin that causes cancer in old age past the reproductive age, though there could be selection for resistance to the acute effects of particular carcinogens. For example, aflatoxin, a mold toxin that presumably arose early in evolution, causes cancer in trout, rats, mice, and monkeys, and probably people, though the species are not equally sensitive. Many of the common metal salts are carcinogens (such as lead, cadmium, beryllium, nickel, chromium, selenium, and arsenic) despite their presence during all of evolution. (ii) Given the enormous variety of plant toxins, most of our defenses may be general defenses against acute effects, such as shedding the surface lining of cells of our digestive and respiratory systems every day; protecting these surfaces with a mucin layer; having detoxifying enzymes that are often inducible, such as cytochrome P-450, conjugating enzymes, and glutathione transferases; and having DNA repair enzymes, which would be useful against a wide variety of ingested toxic chemicals, both natural and synthetic. Some human cancer may be caused by interfering with these normal protective systems. (iii) The human diet has changed drastically in the last few thousand years, and most of us are eating plants (such as coffee, potatoes, tomatoes, and kiwi fruit) that our ancestors did not. (iv) Normal metabolism produces radiomimetic mutagens and carcinogens, such as hydrogen peroxide and other reactive forms of oxygen. Though we have defenses against these agents, they still may be major contributors to aging and cancer. A wide variety of external agents may disturb this balance between damage and defense (12, 42).

Implications for Decision-Making

For all of these considerations, our scale is not a scale of risks to humans but is only a way of setting priorities for concern, which should also take into account the numbers of people exposed. It should be emphasized that it is a linear scale and thus may overestimate low potential hazards if, as we argue above, linearity is not the normal case, or if nongenotoxic carcinogens are not of very much concern at doses much below the toxic dose.

Thus, it is not scientifically credible to use the results from rodent tests done at the MTD to directly estimate human risks at low doses. For example, an EPA "risk assessment" (92) based on a succession of worst case assumptions (several of which are unique to EDB) concluded that EDB residues in grain (HERP = 0.0004%) could cause 3 cases of cancer in 1000 people (about 1% of all U.S. cancer). A consequence was the banning of the main fumigant in the country. It would be more reasonable to compare the possible hazard of EDB residues to that of other common possible hazards.

For example, the aflatoxin in the average peanut butter sandwich, or a raw mushroom, are 75 and 200 times, respectively, the possible hazard of EDB. Before banning EDB, a useful substance with rather low residue levels, it might be reasonable to consider whether the hazards of the alternatives, such as food irradiation, or the consequences of banning, such as increased mold contamination of grain, pose less risk to society. Also, there is a disparity between OSHA not regulating worker exposures at a HERP of 140%, while the EPA bans the substance at a HERP of 0.0004%. In addition, the FDA allows a possible hazard up to a HERP of 0.3% for peanut butter (20 ppb), and there is no warning about buying comfrey pills.

Because of the large background of low-level carcinogenic and other (93) hazards, and the high costs of regulation, priority setting is a critical first step. It is important not to divert society's attention away from the few really serious hazards, such as tobacco or saturated fat (for heart disease), by the pursuit of hundreds of minor or nonexistent hazards. Our knowledge is also more certain about the enormous toll of tobacco—about 350,000 deaths per year (1, 2).

There are many trade-offs to be made in all technologies. Trichloroethylene and tetrachloroethylene (perchloroethylene) replaced hazardous flammable solvents. Modern synthetic pesticides displaced lead arsenate, which was a major pesticide before the modern chemical era. Lead and arsenic are both natural carcinogens. There is also a choice to be made between using synthetic pesticides and raising the level of plant natural toxins by breeding. It is not clear that the latter approach, even where feasible, is preferable. For example, plant breeders produced an insect-resistant potato, which has to be withdrawn from the market because of its acute toxicity to humans due to a high level of the natural plant toxins solanine and chaconine (12).

This analysis on the levels of synthetic pollutants in drinking water and of synthetic pesticide residues in foods suggests that this pollution is likely to be a minimal carcinogenic hazard relative to the background of natural carcinogens. This result is consistent with the epidemiologic evidence (1). Obviously prudence is desirable with regard to pollution, but we do need to work out some balance between chemophobia with its high costs to the national wealth, and sensible management of industrial chemicals (94).

Human life expectancy continues to lengthen in industrial countries, and the longest life expectancy in the world is in Japan, an extremely crowded and industrialized country. U.S. cancer death rates, except for lung cancer due to tobacco and melanoma due to ultraviolet light, are not on the whole increasing and have mostly been steady for 50 years. New progress in cancer research, molecular biology, epidemiology, and biochemical epidemiology (95) will probably continue to increase the understanding necessary for lengthening life-span and decreasing cancer death rates.

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97. A national survey of U.S. drinking water supplies identified the concentrations of about 20 organic compounds. The mean total trihalomethane concentration was 117 µg/liter, with the most common, chloroform, present at a mean concentration of 83 µg/liter (83 ppb). Raw water that is relatively free of organic matter results in drinking water relatively free of trihalomethanes after chlorination. These studies are reviewed in S. J. Williamson, *The Science of the Total Environment* 18, 187 (1981).
98. Public and private drinking water wells in Santa Clara Valley, California, have been found to be contaminated with a variety of halogenated hydrocarbons in small amounts. Among 19 public water system wells, the most commonly found contaminants were trichloroethylene (TCE), and 1,1,2-trichloro-1,2,2-trifluoroethane (Freon-113). TCE was found in 15 wells generally at concentrations of less than 30 ppb, though one well contained up to 8800 ppb, and Freon-113 was found in six wells at concentrations up to 12 ppb. Neither chemical has been adequately tested for carcinogenicity in long-term bioassays. In addition to these compounds, three wells also contained carcinogenic compounds at low concentrations. Water from public supply wells may be mixed with treated surface water before delivery, thus the concentrations of these compounds that people actually receive may be somewhat reduced. Thirty-five private drinking water supply wells were examined; the major contaminant was the carcinogen trichloroethylene (TCE), at levels up to 2800 ppb. TCE and Freon-113 were also found in some wells, at maximum levels of 24 ppb and 40 ppb, respectively. Though lower levels of contaminants from private wells, the contaminant concentrations may be higher because the water is not mixed with water from other sources [California Department of Health Services, California Regional Water Quality Control Board, Santa Clara County Public Health Department, Santa Clara Valley Water District, U.S. Environmental Protection Agency, Ground Water and Drinking Water in the Santa Clara Valley: A White Paper (1984), table 8]. Trichloroethylene may not be a carcinogen in humans at low doses [R. D. Kimbrough, F. L. Mitchell, V. N. Houk, *J. Toxicol. Environ. Health* 18, 369 (1985)].
99. Contaminated drinking water in the area of Woburn, Massachusetts, was found to contain 267 ppb trichloroethylene, 21 ppb trichloroethylene, 12 ppb chloroform, 23 ppb trichloroethylene, and 28 ppb 1,2-dichloroethane [S. W. Lapidus, B. J. Wassen, M. Zelen, *J. Am. Stat. Assoc.* 81, 583 (1986)].
100. The amount of chloroform absorbed by a 6-year-old child in a chlorinated freshwater swimming pool has been estimated [J. A. Berch, *Med. Hypotheses* 6, 303 (1980)]. Table 1 refers to the chloroform in an average pool (150 µg/liter) and for a 27-kg child. Three other trihalomethanes were identified in these freshwater pools: bromoform, bromochloroform, and dichlorodibromomethane. U. Lahl, J. Vonnahme, B. Gabel, B. Seidel, W. Thumann [Water Res. 18, 603 (1981)] have estimated absorption in covered swimming pools.
101. J. McCann, L. Horn, J. Gorman, A. V. Nopp, in *Short-Term Biomarkers in the Analysis of Complex Environmental Mixtures*, V. S. Sandhu, D. M. De Marinis, M. I. Man, M. M. Moore, J. L. Mumford, Eds. (Plenum, New York, in press). This estimate (Table 1) for formaldehyde in conventional homes, excludes foam-molded houses and mobile homes. The figure is a mean of the median or mean of the reported samples in each paper. For benzene, the figure is a mean of all reported median or mean samples. The level of benzene in Los Angeles outdoor air is similar [U.S. EPA Office of Air Quality Planning and Standards, EPA 450/4-86-012, 1986].
102. The average adult daily PCB intake from food estimated by the FDA in fiscal years 1981-1982 was 0.2 µg/kg/day. Mean highly different PCB mixtures have been studied in long-term animal cancer bioassays; the calculation of TD₅₀ was from a test of Aroclor 1260 which was more potent than other PCBs (14).
103. The average consumption of EDB residues in grams has been estimated by the EPA for adults as 0.006 µg/kg/day and for children as 0.013 µg/kg/day [U.S. EPA Office of Pesticide Programs, *Estimate of Dietary EDB Residue: Support and Decade Document for Green and Green Allowing European Use* (8 February 1984)].
104. The leaves and roots of Russian comfrey are widely sold in health food stores and are consumed as a medicinal herb or salad plant or are brewed as a tea. Comfrey leaf has been shown to contain 0.01 to 0.15% by weight, total pyrene-like alkaloids, with an average level of 0.06% for intermediate size leaves (C. I. Cuhner, J. A. Edgar, J. L. Frahn, L. W. Smith, *Am. J. Chem.* 33, 1105 (1980)). The main pyrene-like alkaloids present in comfrey leaves are echinone and 7-acetyrychone, neither of which has been tested for carcinogenicity. Almost all tested 1,2-unsaturated pyrene-like alkaloids have been shown to be genotoxic and carcinogenic [H. Mori et al., *Cancer Res* 46, 3125 (1986)]. Symptomatic accounts for 5% of the total alkaloid in the tea and has been shown to be carcinogenic [C. I. Cuhner et al., *Experientia* 36, 37 (1980)]. We assume that 1.5 g of intermediate size leaves are used per cup of comfrey tea (Table 1). The primary alkaloids in comfrey roots are symphytine (0.6% per kilogram of roots) and echinone (0.5% per kilogram of roots) [T. Furuta and M. Hatake, *Phytochemistry* 18, 2217 (1971)]. Comfrey-pyrene tablets (300 mg of root per tablet) have a recommended dose of one to three tablets three times per day. Comfrey roots and leaves both induce liver tumors in rats [I. Hirota, H. Mori, M. Hagi, *J. Natl. Cancer Inst.* 61, 865 (1978)], and the TD₅₀ value is based on these results. These pyrene-like alkaloids tested have been found to be at least

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DEPARTMENT OF BIOCHEMISTRY

BERKELEY, CALIFORNIA 94720

June 26, 1987

Dr. Charles M. Benbrook
 Executive Director
 Board on Agriculture
 National Research Council
 2101 Constitution Avenue, N.W.
 Washington, D.C. 20418

Dear Dr. Benbrook:

You have been criticizing our work erroneously, and this letter is a request to read our recent paper in Science more carefully, and to think more deeply about the implications for the NAS-NRC report on pesticides.

In the June issue of Insight magazine, you are quoted as saying, "I don't think there are any natural products that would come anywhere near the magnitude of the risk of EDB in oranges and grain at the levels it was found prior to its cancellation." One of the main points of our Science paper was to show that this is not true. The residue levels we used for EDB in grain were taken from the EPA document justifying the ban of EDB. These were actual levels on what the American public was consuming at the time of the ban. Our HERP index value for this intake, 0.0004%, is trivial compared to many commonly consumed natural substances reported in the table in Science. The residue of EDB on oranges is primarily on the skin, and the intake was even less than from grain. The HERP index is a ratio of the human exposure dose (in mg/kg/day) to the carcinogenic potency in rodents (in mg/kg/day) reported as a percentage.

In our paper we emphasized that the potential hazards from pesticide residues should be viewed in the context of many larger natural exposures and that it is not scientifically credible to use the results from rodent tests done at the MTD to directly estimate human risks at low doses. We said,

"For example, an EPA "risk assessment" (92) based on a succession of worst case assumptions (several of which are unique to EDB) concluded that EDB residues in grain (HERP = 0.0004%) could cause 3 cases of cancer in 1000 people (about 1% of all U.S. cancer). A consequence was the banning of the main fumigant in the country. It would be more reasonable to compare the possible hazard of EDB residues to that of other common possible hazards. For example, the aflatoxin in the average peanut butter sandwich, or a raw mushroom, are 75 and 200 times, respectively,

the possible hazard of EDB. Before banning EDB, a useful substance with rather low residue levels, it might be reasonable to consider whether the hazards of the alternatives, such as food irradiation, or the consequences of banning, such as increased mold contamination of grain, pose less risk to society...."

The paper, and my previous paper in Science, also point out that we are eating 10 000 times more of nature's pesticides daily than man-made pesticides and that only a handful of these have been tested in animal cancer tests. The frequency of positive results in animal bioassays is high for both nature pesticides and man-made pesticides (40-60%) so there is every reason to think we will find a whole new world of carcinogens among the natural chemicals when more are tested. We are now compiling a long list of the natural chemicals we think should be tested, and we are impressed with how large are the amounts ingested and how close most are to the toxic level. Our paper points out the case of solanine and chaconine:

"...Solanine and chaconine (the main alkaloids in potatoes) are cholinesterase inhibitors and were introduced generally into the human diet about 400 years ago with the dissemination of the potato from the Andes. They can be detected in the blood of almost all people (12,90). Total alkaloids are present at a level of 15 000 µg per 200-g potato with not a large safety factor (about sixfold) from the toxic level for humans (91). No other alkaloid has been tested for carcinogenicity. By contrast, malathion the main synthetic organophosphate cholinesterase inhibitor in our diet (17 µg/day)(16), is not a carcinogen in rodents."

"...There is also a choice to be made between using synthetic pesticides and raising the level of plants' natural toxins by breeding. It is not clear that the latter approach, even where feasible, is preferable. For example plant breeders produced an insect-resistant potato which had to be withdrawn from the market because of its acute toxicity to humans due to a high level of the natural plant toxins solanine and chaconine 2)."

Thus, in your report you point out that tomatoes are allowed to have the most residues, and you also say, "Advances in classical plant breeding...offer some promise for nonchemical pest control in the future. Nonchemical approaches will be encouraged by tolerance revocations if more profitable chemical controls are not available...." I don't think you would have made such a statement if you had read and absorbed my 1983 Science paper (Vol. 221, pp. 1256-1264). Of course, tomatine, one of the alkaloids in tomatoes, is a chemical, too. It is untested in rodent cancer bioassays and is present at 36 000 µg/100 g tomato and is orders of magnitude closer to the toxic level (as are solanine and chaconine) than are man-made pesticide residues.

In the New York Times you were quoted as dismissing our work because we didn't have the latest data. We are not certain whether you were referring to residue data or the results of animal bioassays. With respect to the residue levels we did use the latest published FDA data on actual pesticide residues found in food. Residue data was available for only a few of the chemicals that you evaluated in the NAS report. For our purposes it would be useful to have more published data on actual residues. The methodology in your report did a different thing: hypothetical worst-case analyses assuming that every farmer used every possible allowable pesticide at the maximum allowable

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residue levels. I do think, by the way, that it was quite useful and reasonable for you people to have analyzed permissible residue levels and thought there was much useful material in your report. We have used permissible levels for worker exposures in a recently submitted paper on PERP values [Permissible Exposure/Rodent Potency as contrasted with our HERP values actual exposure]] for occupational exposures to carcinogens, which often come out extremely high, incidentally

We of course realize that the latest actual exposure figures from the FDA which we quoted don't include every possible pesticide, but they are a reasonable attempt, and we haven't seen any results including your own that our estimate of 45 µg of possibly carcinogenic pesticide residues consumed in a day (assuming everything not tested will be a carcinogen) is going to be very far off. For comparison we also mention in our paper that there are about 500 µg of carcinogens in a cup of coffee (hydrogen peroxide and methylglyoxal), 185 µg of carcinogenic formaldehyde in a slice of bread, 10 times more formaldehyde in a cola, 760 µg of carcinogenic estragole in a basil leaf, a gram of burnt material from cooking our food, nitrosamines formed in our gas ovens, etc.

With respect to animal bioassay data, the NAS report does calculate Q* with animal bioassay data that are not in the published literature and that we would like very much to have for our Carcinogenic Potency Database. Do you know how we might obtain these data? We have converted your Q* and TMRC values to approximate our PERP index, and we calculate that all of the permissible risks in the NAS report lumped together produce a PERP value about the equivalent of consuming (HERP) the alcohol in one glass of wine per week. This sort of comparative analysis, and not using the word "risk" for mathematical juggling in the dark, will help to prevent people from converting your numbers to absurdities. Lawrie Mott of the Natural Resources Defense Council for example was quoted by the New York Times as saying, "Using the worst-case risk estimates, the number of cancer cases caused by the 28 pesticides in this country 1.46 million over the 70-year lifetime exposure. But...the risk numbers 'significantly understate' the perils of cancer to consumers...."

I am not terribly concerned, as pointed out in the paper, about the carcinogenic risks from basil leaves and peanut butter sandwiches as don't believe any of these hypothetical worst-case risks far from the toxic dose will have much relation to reality. Our paper discusses the work of Farber and others, which suggests that a mutated oncogene in the liver isn't enough for carcinogenesis and that you need clonal selection (promotion which you can get through toxicity. I think one is commonly supplying toxicity in animal tests by using the maximum tolerated dose and therefore that the true dose response will fall off sharply with dose. I think we should be looking more for toxicity reactions (hepatitis B, alcoholic cirrhosis, sunburn, etc.) in human cancer.

I am becoming convinced, though I won't go into detail here, that attempting to regulate carcinogens at 0-6 lifetime) hypothetical worst-case risks, though better than a Delaney approach, is counterproductive for several reasons. The world is full of risks much above that, so paying attention to minor risks diverts scientists and regulators from more serious and productive work, thus decreasing public health. Public health is also decreased when one confuses the public so that they lose sight of what is important in the

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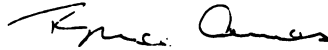
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plethora of risks. Since epidemiological evidence on disease indicates that we should be eating more fruit and vegetables, not less, raising their prices may be costly in terms of public health. If the levels of natural pesticides are raised closer to the toxic level by plant breeding, an inevitable consequence of eliminating man-made pesticides, this will probably decrease public health as well.

I enclose a recent article on one of the most eminent epidemiologists' reservations about "risk assessment" and some of my writings that you should find of interest. I would appreciate a copy of the clarification letter you send to Insight about the quote I started this letter with. Do come visit if you are here in the Bay Area. We have some mutual interests to discuss. As an inducement, I'll tell you about the natural compound we are all eating in large amounts that has many of the properties of dioxin.

Yours truly,



Bruce N. Ames
Professor and Chairman

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DEPARTMENT OF BIOCHEMISTRY

BERKELEY, CALIFORNIA 94720

July 24, 1987

Dr. Charles M. Banbrook
 Executive Director
 Board on Agriculture
 National Research Council
 2101 Constitution Avenue, N.W.
 Washington, D.C. 20418

Dear Dr. Banbrook:

In my letter to you of June 26, I would like to correct one sentence. We calculated the equivalent of all of your permissible hazards lumped together as the equivalent of the alcohol in 2 beers a year. This number was based on using the numbers from your Tables 3-17, 3-18, and 3-19. These Tables indicate the dose as mg pesticide. This is an error in your Tables, and our calculation is therefore incorrect. It should be mg/kg, which is indicated in your Appendix B. When we noticed the discrepancy, we made some phone calls to check which part of your report was correct and have determined that it is Appendix B. My sentence should therefore read:

"We have converted your Q* and TMRC values to approximate our PERP index, and we calculate that all of the permissible risks in the NAS report lumped together produce a PERP value about the equivalent of consuming (HERP) the alcohol in one glass of wine per week."

I enclose a revised page 3 of my letter as a substitute for your files. I await your reply to my letter.

Yours truly,

Bruce N. Ames
 Professor and Chairman

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cc: National Research Council Committee
 (w/enclosure)

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BOARD ON AGRICULTURE

TELEPHONE
(202) 334-3062

August 3, 1987

Dr. Bruce Ames
Chairman
Department of Biochemistry
University of California - Berkeley
Berkeley, CA 94720

Dear Dr. Ames:

Thank you for your provocative letter of June 26. My apologies for not responding sooner--we have spent the last two weeks settling into a new building.

Your letter raises so many interesting issues and challenges, I hardly know where to begin. I am certain that your Science article stimulated thinking and research in the appropriate disciplines and that it will no doubt continue to be a topic for discussion and debate both in scientific and regulatory circles. The Board on Agriculture's recent report on pesticide residues in food will also be the topic of future analysis and debate. The end result of your article and our report should be a more informed judgment and rational regulation of possible carcinogenic substances in food.

Let me briefly clarify the objectives of the NRC report. The committee's charge was to analyze the impact of the Delaney Clause on the pesticide tolerance setting system and to provide EPA with a means to analyze these effects. It was not our objective to rank the relative risks of pesticides or foods based on actual residues. Data gaps prevent such a comparative risk assessment using actual or even anticipated residue data.

The worst-case rankings contained in the report are only meaningful when viewed in the larger context of the committee's charge. The worst-case risk methodologies underlying the committee's analysis were the only way the committee could empirically answer questions basic to its charge regarding the nature and distribution of potential oncogenic risk in different kinds of foods. The committee had no choice but to use EPA's TMRC exposure estimates in conducting its analysis. Actual residue data is available on relatively few pesticides, and often for only some of the crops on which these pesticides are registered. Selective incorporation of actual residue data for some of the 28 pesticides studied in depth would have biased the results.

Moreover, the committee lacked confidence in the consistency and representativeness of the "actual residue data." Depending upon who

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requests or develops the data, the analytical methods and procedures underlying the measurement of "actual residue data" may differ markedly. You will soon discover this as you compile an actual residue database for pesticide risk assessment.

In view of these limitations, the committee decided after a year and a half of discussion that it had two options: It could report its analytical findings based on the TMRC methodology, or it could include essentially no findings in the report, presenting only its sense of the distribution and potential risk from herbicides, insecticides, fungicides, old and new pesticides and residues in raw versus processed foods. After considerable internal discussion the committee was convinced of the validity of the report's basic findings despite the fact that the committee knew the data might be used to misrepresent the committee's findings. Moreover, the findings led directly to important recommendations which would have no basis without the justification inherent in the tables and analysis in Chapters 3, 4, and 5.

In your recent Science article, the analysis of pesticide exposure focuses on relatively few pesticides--those detected by FDA in one of its market basket surveys. You are aware I am sure, of the many deficiencies in FDA's testing methods both in terms of sample size and residues detected. As a result, your conclusions are limited to the quality of this data. Likewise the NRC report's "worst-case"/"permissible level" risk assessments have come under similar criticisms. We are all limited by the quality and completeness of data on pesticide toxicity and dietary exposure. The tables and lists presented in our report are all based on risks associated with permissible levels of residues. They are primarily intended to demonstrate the distribution of risk and the merit of distinguishing between possible "big" risks in contrast to certain "de minimus" risks, and to demonstrate to EPA the types of analyses that may be useful in devising a more rational regulatory program for pesticide residues in food.

The committee agrees that cancer risk from other sources is greater than risks posed by pesticides, but would argue that this conclusion is not particularly relevant to its charge, which was to offer EPA suggestions on how to assess options for regulating cancer causing pesticide residues in food. Whether cigarettes or comfrey tea present greater risks than pesticides is not germane to the analysis. It is however an issue readily addressed in the context of the NRC report's analytical framework, and the regulatory implications of which may be evaluated using the principles inherent in the report's recommendations. If a consensus emerges and cancer risk from natural contaminants or constituents in foods pose greater risk than pesticides, this recognition will challenge Congress, federal agencies, and the public to confront many basic assumptions about how public health can and should be improved.

Dr. Bruce Ames
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The basic point of your letter, as I understand it, is that some natural carcinogens are much worse than most, if not all, tested synthetic chemicals. Such a judgment must ultimately rest upon knowledge of both dose and toxicological potency and many other factors that may intervene in determining how humans respond to exposure to various agents. Some scientists also theorize that humans have developed a degree of "genetic resistance" to some natural carcinogens. I've read persuasive argument on several sides of these issues including the important points you and your colleagues made in response to letters following the 1983 *Science* article. I am not aware of recent evidence that has shifted markedly the center of these debates. I would greatly appreciate your views on significant new developments in the sciences underlying risk assessment and pertinent to these issues.

You state that regulatory actions against most pesticides are hard to justify in terms of relative risk reduction achieved. I am a strong believer in the concept of relative risk and attach a recent paper articulating in more detail how I envision relative risk decision-making within the context of FIFRA. I am most anxious however to gain a firmer sense of how fast a consensus within the scientific community might emerge in support of your basic hypothesis and when it does the implications for EPA/FDA and FIFRA/FDCA will be profound indeed almost unimaginable. I'm sure you and others will encounter a whole new set of challenges in forging a political consensus for fundamental change in regulatory priorities.

I'd like to raise a few questions regarding the substance of your letter. I am unsure of the exposure estimates used to derive HERP rankings. In your letter you say that if every pesticide not tested is assumed carcinogenic then a reasonable estimate of carcinogenic pesticide residue in the diet will be 45 ug. Is this per day for an "average" diet? How did you calculate this number? In your most recent *Science* article you note that exposure to three noncarcinogenic compounds is 105 ug; more than twice the exposure you estimate for all carcinogenic and all untested pesticides (based on the assumption that they will all be positive). Your method of estimating dietary exposure to pesticides from FDA market basket results is one way to develop a rough estimate of exposure. The completeness and accuracy of this method is constrained by the extent of coverage and accuracy of the FDA surveys.

Another perspective on total exposure can be gained by working back from "worst-case" estimates. For the 28 pesticides we studied in depth, total "worst-case" THRC exposure for a 70 kg adult is 53.7 mg per day. If actual residues are 10% of tolerance levels, and if 10% of the possible acres are treated on average "anticipated" total exposure would be 0.537 mg/day. Different assumptions will of course, yield different estimates. Your 45 ug estimate, if I interpret it correctly, would arise from an assumption that about 1% of acres are treated, with residues at 10% of the

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tolerance level. One must also consider wide variation in exposure based on regional- or age-based differences in diet. The TMRC calculation assumes an average adult diet with no regional or other variation.

You may note that EPA special review and/or re-registration documents, another important source of more accurate exposure data on pesticides, indicate that in general "most likely" or "anticipated residue" levels are between 1/100 and 1/10 of TMRC exposure estimates. Some major products of concern--the EBDCs, benomyl, alachlor, for example--have anticipated residues at about 10% of TMRC. Residues of certain compounds, such as the EBDC metabolite and conversion product ETU, will increase during cooking and after ingestion, making assessment of actual exposure and risk more complex.

As you note in your letter, it is incorrect to assume that absence of detection by FDA is proof of absence from the food supply. Of the 28 oncogenic pesticides we studied in depth (for which EPA could supply Q⁺'s), about one-third are not detected by either of the two methods routinely used by FDA. At least 14 of the 53 pesticides on the so-called Waxman list are not detected by FDA's routine multiresidue screens. A recent GAO report documents the range of sensitivity of FDA's residue tests (Pesticides: Need to Enhance FDA's Ability to Protect the Public from Illegal Residues GAO/RCED 8707 October 1986). Most importantly, FDA's multiresidue tests do not cover some of the most worrisome and widely used oncogenic pesticides--particularly fungicides used on fruits and vegetables. Furthermore, in no case does FDA look for oncogenic metabolites or conversion products that are known or suspected oncogens.

I am intrigued by your method for calculating the TD₅₀ index. Would you please provide, as an example, your calculations for EDB, and formaldehyde, and for the pesticides atrazine and alachlor (summary data from these two pesticides is enclosed). In particular I am not certain how the TD₅₀ is extrapolated from the animal data and how several studies are combined. Is the least squares method always used? Although I do not thoroughly understand the TD₅₀, I agree that a measurement of it type will be useful for ranking the potency of carcinogenic compounds and also in the formulation of sound public policy.

I maintain that worst-case estimates are not entirely irrelevant scientifically or in a regulatory context. They serve as an estimate of potential risk among more highly sensitive or highly exposed population groups, i.e. sensitive individuals who eat a lot of local fresh fruits and vegetables, all of which may have been treated with a specific set of pesticides, sometimes at rates and in ways that increase anticipated residue levels above "normal" levels. In future work the Board hopes to push ahead with the incorporation of "actual" or "anticipated" residue data in our database. We'd like to add water-based exposure to our dataset and undertake a study on exposure and hazard for children (proposal enclosed as approved by the NRC).

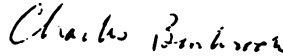
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I'd like to discuss a joint effort to expand and refine the assessment and comparison of natural versus synthetic risks. Upon reviewing your HERP calculation, I suggest developing a modified HERP index based on a Q^* potency indicator and our collective data sets for additional pesticides and natural contaminants. The goal of this exercise would be to compare natural and chemical risks using analytically comparable methods and consistent assumptions in exposure estimates. The Board on Agriculture is meeting in November in conjunction with the opening ceremonies for the Plant Gene Expression Center in Berkeley. Perhaps we can get together that week to discuss this venture further.

We would be glad to share with you and your colleagues other data in our files on pesticides. I might note that a member of the Board's staff, Richard Wiles, has spoken with Lois Swirsky Gold concerning EPA's Q^* 's and their derivation from animal data. Please give me a call at 202/334-3062 so we can discuss these intriguing questions in greater depth and the possibility of getting together in Berkeley.

Sincerely,



Charles M. Benbrook
Executive Director

Attachments

A CASE-CONTROL STUDY OF BRAIN GLIOMAS AND OCCUPATIONAL EXPOSURE TO CHEMICAL CARCINOGENS: THE RISK TO FARMERS

MASSIMO MUSICCO,¹ MILENA SANT,² SILVIA MOLINARI,¹
GRAZIELLA FILIPPINI,¹ GEMMA GATTA,² AND FRANCO BERRINO²

Musicco, M. (National Research Council, 20133 Milano, Italy), M. Sant, S. Molinari, G. Filippini, G. Gatta, and F. Berrino. A case-control study of brain gliomas and occupational exposure to chemical carcinogens: the risk to farmers. *Am J Epidemiol* 1988;128:778-85.

During 1983 and 1984, 240 newly diagnosed cases of brain glioma and 742 controls (465 non-glioma nervous system tumors and 277 patients with other neurologic diseases) were recruited and interviewed in the neurologic and neurosurgical departments of two hospitals in Milan, Italy. The occupational histories of cases and controls were compared, and relative risk estimates, adjusted for sex, age, residence, and socioeconomic status, were computed using the Mantel-Haenszel method. A statistically significant risk increase was found for farmers (relative risk (RR) = 1.6, $p = 0.0025$). This risk increase was attributable to those farmers who reported the use of chemicals (insecticides or fungicides, herbicides, and fertilizers). Among the three groups of investigated agrochemicals, only the use of insecticides or fungicides was associated with a significant increase in relative risk (RR = 2.0, $p = 0.006$). Many farmers exposed to fungicides reported the use of commercial compounds of copper sulfate. Some of these compounds contain methyl urea, which has a specific carcinogenic effect on the nervous system in animals. These data suggest that the occupational exposure of farmers to agrochemicals might be responsible for the observed excess risk of brain glioma in farmers.

agriculture; glioma; insecticides; occupational diseases

The evidence of the existence of chemical carcinogens for the nervous system is supported by a large amount of data. In the experimental setting, some *N*-nitroso compounds (mainly *N*-nitroso alkyl ureas) are capable of inducing tumors of the nervous system in animals (1). In humans, a number of observational studies and case reports have reported associations between brain

tumors and occupational and nonoccupational exposure to vinyl chloride (2-4), *N*-nitroso compounds (5-7), pesticides (8-10) and formaldehyde (11, 12). A recent hospital-based case-control study (13) showed an increased relative risk for occupation in the rubber industry and for some indicators of dietary and nondietary exposure to *N*-nitroso compounds, together with a protective effect of fruit.

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² Istituto Nazionale per lo Studio e la Cura dei Tumori, Milano, Italy.

³ Istituto Neurologico "C. Besta", Milano, Italy.

(The complete article is held in the committee files.)

Herbicides and Cancer:
A Review and Discussion of Methodologic Issues

Aaron Blair and Shelia Hoar Zahm
Occupational Studies Section
National Cancer Institute

June, 1988

Presented at the International Symposium
on
Occupational Cancer Epidemiology
Vancouver, British Columbia

In the late 1970s and early 1980s, investigators in Sweden reported over 5-fold risks for soft-tissue sarcoma and lymphoma among persons exposed to phenoxyacetic acid herbicides and chlorophenols (10-12). The possibility that these widely used and important commercial chemicals might be human carcinogens prompted a number of epidemiologic investigations. Reports from over 20 additional studies are now available. Results from these investigations, which employed cohort and case-control designs, have not been consistent, but as of yet the discrepancies cannot be explained. The purpose of this paper is to provide a brief overview of available findings, to note consistencies and inconsistencies, to consider methodologic issues, particularly for case-control studies that might account for these inconsistencies, and to identify areas of research needing development.

(The complete report is held in the committee files.)

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DEPARTMENT OF BIOCHEMISTRY

BERKELEY, CALIFORNIA 94720

July 24, 1987

Dr. Charles M. Benbrook
Executive Director
Board on Agriculture
National Research Council
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Dear Dr. Benbrook:

In my letter to you of June 26, I would like to correct one sentence. We calculated the equivalent of all of your permissible hazards lumped together as the equivalent of the alcohol in 2 beers a year. This number was based on using the numbers from your Tables 3-17, 3-18, and 3-19. These Tables indicate the dose as mg pesticide. This is an error in your Tables, and our calculation is therefore incorrect. It should be mg/kg, which is indicated in your Appendix B. When we noticed the discrepancy, we made some phone calls to check which part of your report was correct and have determined that it is Appendix B. My sentence should therefore read:

"We have converted your Q* and TMRC values to approximate our PERP index, and we calculate that all of the permissible risks in the NAS report lumped together produce a PERP value about the equivalent of consuming (HERP) the alcohol in one glass of wine per week."

I enclose a revised page 3 of my letter as a substitute for your files. I await your reply to my letter.

Yours truly,

Bruce N. Ames
Professor and Chairman

BNA/ask
Enclosure

cc: National Research Council Committee
(w/enclosure)

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SANTA BARBARA • SANTA CRUZ

DEPARTMENT OF BIOCHEMISTRY

BERKELEY, CALIFORNIA 94720

June 26, 1987

Dr. Charles M. Benbrook
 Executive Director
 Board on Agriculture
 National Research Council
 2101 Constitution Avenue, N.W.
 Washington, D.C. 20418

Dear Dr. Benbrook:

You have been criticizing our work erroneously, and this letter is a request to read our recent paper in Science more carefully and to think more deeply about the implications for the NAS-NRC report on pesticides.

In the June issue of Insight magazine, you are quoted as saying, "I don't think there are any natural products that would come anywhere near the magnitude of the risk of EDB in oranges and grain at the levels it was found prior to its cancellation." One of the main points of our Science paper was to show that this is not true. The residue levels we used for EDB in grain were taken from the EPA document justifying the ban of EDB. These were actual levels on what the American public was consuming at the time of the ban. Our HERP index value for this intake, 0.0004%, is trivial compared to many commonly consumed natural substances reported in the table in Science. The residue of EDB on oranges is primarily on the skin, and the intake was even less than from grain. The HERP index is a ratio of the human exposure dose in mg/kg/day to the carcinogenic potency in rodents (in mg/kg/day) reported as a percentage.

In our paper we emphasized that the potential hazards from pesticide residues should be viewed in the context of many larger natural exposures and that it is not scientifically credible to use the results from rodent tests done at the MTD to directly estimate human risks at low doses. We said,

"For example, an EPA "risk assessment" (92) based on a succession of worst case assumptions (several of which are unique to EDB) concluded that EDB residues in grain (HERP 0.0004%) could cause 3 cases of cancer in 1000 people (about 1% of all U.S. cancer). A consequence was the banning of the main fumigant in the country. It would be more reasonable to compare the possible hazard of EDB residues to that of other common possible hazards. For example, the aflatoxin in the average peanut butter sandwich, or a raw mushroom, are 75 and 200 times, respectively,

the possible hazard of EDB. Before banning EDB, a useful substance with rather low residue levels, it might be reasonable to consider whether the hazards of the alternatives, such as food irradiation, or the consequences of banning, such as increased mold contamination of grain, pose less risk to society...."

The paper, and my previous paper in Science, also point out that we are eating 1,000 times more of nature's pesticides daily than man-made pesticides and that only a handful of these have been tested in animal cancer tests. The frequency of positive results in animal bioassays is high for both natural pesticides and man-made pesticides (40-60% so there is every reason to think we will find a whole new world of carcinogens among the natural chemicals when more are tested. We are slowly compiling a long list of the natural chemicals we think should be tested and we are impressed with how large are the amounts ingested and how close most are to the toxic level. Our paper points out the case of solanine and chaconine

"...Solanine and chaconine (the main alkaloids in potatoes) are cholinesterase inhibitors and were introduced generally into the human diet about 400 years ago with the dissemination of the potato from the Andes. They can be detected in the blood of almost all people (12 90). Total alkaloids are present at a level of 15 000 µg per 200-g potato with not a large safety factor (about sixfold) from the toxic level for humans (91). Neither alkaloid has been tested for carcinogenicity. By contrast, malathion the main synthetic organophosphate cholinesterase inhibitor in our diet (17 µg/day)(16), is not a carcinogen in rodents."

"...There is also a choice to be made between using synthetic pesticides and raising the level of plants' natural toxins by breeding. It is not clear that the latter approach, even where feasible, is preferable. For example, plant breeders produced an insect-resistant potato which had to be withdrawn from the market because of its acute toxicity to humans due to a high level of the natural plant toxins solanine and chaconine (2)."

Thus, in your report you point out that tomatoes are allowed to have the most residues, and you also say "Advances in classical plant breeding...offer some promise for nonchemical pest control in the future. Nonchemical approaches will be encouraged by tolerance revocations if more profitable chemical controls are not available...." I don't think you would have made such a statement if you had read and absorbed my 1983 Science paper (Vol. 221, pp. 1256-1264). Of course, tomatine, one of the alkaloids in tomatoes, is a chemical, too. It is untested in rodent cancer bioassays and is present at 36,000 µg/100 g tomato and is orders of magnitude closer to the toxic level (as are solanine and chaconine) than are man-made pesticide residues.

In the New York Times you were quoted as dismissing our work because we didn't have the latest data. We are not certain whether you were referring to residue data or the results of animal bioassays. With respect to the residue levels we did use the latest published FDA data on actual pesticide residues found in food. Residue data was available for only a few of the chemicals that you evaluated in the NAS report. For our purposes, it would be useful to have more published data on actual residues. The methodology in your report did a different thing: hypothetical worst-case analyses assuming that every farmer used every possible allowable pesticide at the maximum allowable

Dr. Charles M. Benbrook

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(revised 7/24/87)

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residue levels. I do think, by the way, that it was quite useful and reasonable for you people to have analyzed permissible residue levels and thought there was much useful material in your report. We have used permissible levels for worker exposures in a recently submitted paper on PERP values. Permissible Exposure/Rodent Potency as contrasted with our HERP values (actual exposure) for occupational exposures to carcinogens, which often come out extremely high, incidentally.

We, of course, realize that the latest actual exposure figures from the FDA which we quoted don't include every possible pesticide, but they are a reasonable attempt and we haven't seen any results (including your own) that our estimate of 45 μg of possibly carcinogenic pesticide residues consumed in a day assuming everything not tested will be a carcinogen is going to be very far off. For comparison, we also mention in our paper that there are about 500 μg of carcinogens in a cup of coffee (hydrogen peroxide and methylglyoxal), 185 μg of carcinogenic formaldehyde in a slice of bread, 10 times more formaldehyde in a cola, 760 μg of carcinogenic estragole in a basil leaf, a gram of burnt material from cooking our food, nitrosamines formed in our gas ovens, etc.

With respect to animal bioassay data, the NAS report does calculate Q^* with animal bioassay data that are not in the published literature and that we would like very much to have for our Carcinogenic Potency Database. Do you know how we might obtain these data? We have converted your Q^* and TMRC values to approximate our PERP index, and we calculate that all of the permissible risks in the NAS report lumped together produce a PERP value about the equivalent of consuming (HERP) the alcohol in one glass of wine per week. This sort of comparative analysis, and not using the word "risk" for mathematical juggling in the dark, will help to prevent people from converting your numbers to absurdities. Lawrie Mott of the Natural Resources Defense Council, for example, was quoted by the New York Times as saying, "Using the worst-case risk estimates the number of cancer cases caused by the 28 pesticides in this country is 1.46 million over the 70-year lifetime exposure. But...the risk numbers 'significantly understate' the perils of cancer to consumers...."

I am not terribly concerned, as pointed out in the paper, about the carcinogenic risks from basil leaves and peanut butter sandwiches as I don't believe any of these hypothetical worst-case risks far from the toxic dose will have much relation to reality. Our paper discusses the work of Farber and others, which suggests that a mutated oncogene in the liver isn't enough for carcinogenesis and that you need clonal selection (promotion) which you can get through toxicity. I think one is commonly supplying toxicity in animal tests by using the maximum tolerated dose and therefore that the true dose response will fall off sharply with dose. I think we should be looking more for toxicity reactions (hepatitis B, alcoholic cirrhosis, sunburn, etc.) in human cancer.

I am becoming convinced, though I won't go into detail here, that attempting to regulate carcinogens at 10^{-6} (lifetime) hypothetical worst-case risks, though better than a Delaney approach, is counterproductive for several reasons. The world is full of risks much above that so paying attention to minor risks diverts scientists and regulators from more serious and productive work, thus decreasing public health. Public health is also decreased when one confuses the public so that they lose sight of what is important in the

Dr. Charles M. Benbrook

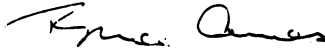
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June 26, 1987

plethora of risks. Since epidemiological evidence on disease indicates that we should be eating more fruit and vegetables, not less, raising their prices may be costly in terms of public health. If the levels of natural pesticides are raised closer to the toxic level by plant breeding, an inevitable consequence of eliminating man-made pesticides, this will probably decrease public health as well.

I enclose a recent article on one of the most eminent epidemiologists' reservations about "risk assessment" and some of my writings that you should find of interest. I would appreciate a copy of the clarification letter you send to Insight about the quote I started this letter with. Do come visit if you are here in the Bay Area. We have some mutual interests to discuss. As an inducement, I'll tell you about the natural compound we are all eating in large amounts that has many of the properties of dioxin.

Yours truly,



Bruce N. Ames
Professor and Chairman

BNA/ssk
Enclosures
Peto
Water II
Science Review
Ranking

cc: National Research Council Committee
(w/enclosures)

Mr. BENBROOK. Just to help put things in perspective somewhat, the best job we can do, given the state of epidemiology, is estimate that for different cancers, we are aware of different causative agents, but as sort of a general matter, about 30—and perhaps as high as 50 percent of cancers are caused by something in the diet, dietary factors, whether it is fat, saturated fat, total calories, cholesterol or something in the fat, or pesticides, no one really knows how to break down what it is about the diet, whether it is calories, et cetera, that is the causative agent and I think it is going to be quite a long time before that science is fully clarified.

Mr. BROWN. The information that you can submit will be helpful. It goes beyond just natural or man-made. It goes to the point that there are man-made carcinogens that impact upon human beings other than through the route of diet, or from the results of the application of pesticides. There are a lot of other ways in which man-made carcinogens can impact upon human beings.

Mr. Grandy, do you have any questions?

Mr. GRANDY. Yes, I do, Mr. Chairman. Thank you.

Dr. Benbrook, I wanted to pursue one aspect of the Delaney Clause which I find confusing and perhaps you could give us your views on this.

It is my understanding that under the Delaney Clause, it would be possible to reregister and authorize as supposedly safe a pesticide that contained a mild carcinogen, and at the same time—in other words, you would eliminate a mild carcinogen, consider it maybe more safe, and at the same time, as you are eliminating that mild carcinogen, you are avoiding or accepting into the food supply a pesticide which may not be a carcinogen, but may be more dangerous. Is that correct?

Mr. BENBROOK. That is correct, Mr. Grandy. In fact, you could be allowing continued use of a carcinogen that is clearly more potent than the one that you are not allowing on the market—

Mr. GRANDY. Could you give the committee an example.

Mr. BENBROOK. Let me give you a specific example. There is a particular fungicide, a new fungicide, that was developed because the agricultural industry has known for years that most of our current fungicides are quite toxic. Eight of 11 are carcinogens. One was developed by a particular company that, when fully tested, caused very mild—some would say equivocal carcinogenic effect. The data was such that scientists could argue back and forth whether it poses any carcinogenic risk, but if you did a risk assessment upon it and came up with a risk number for this fungicide's use on hops, the carcinogenic risk that this new fungicide would have posed was on the order of—if my memory serves me correctly—of a 10 to the minus 8 or 9, so this would be 1/100th of a 1 in a million negligible risk standard.

At the same time, the major older fungicide that remains in use on hops today poses a risk of approximately 10 to the minus 4, or 1 in 10,000. The reason that the new product was not allowed on the market is that it was fully tested before EPA made a regulatory decision to register its use on hops, and it was determined that the level of the residue of the fungicide in the hops concentrates as you manufacture beer, thereby triggering the Delaney Clause which says there shall be zero, or no risk added to the food supply. But

the older product, which wasn't tested until the early 1970's and was in use 20 years before it ever was tested for cancer, it remains on the market basically untouched by the Delaney Clause because the Delaney Clause has never once been applied retroactively to any product on the market.

This is what gave rise to the Academy recommendation that whatever standard you have, it should be applied consistently to both new and old pesticides, because what you have now is a serious bias against anything new.

Mr. GRANDY. So do I understand Roberts-Brown to address that through the reregistration and registration equivalent?

Mr. BENBROOK. It does it there and it also does it by establishing a consistent negligible-risk standard to be applied whenever evaluating dietary cancer risk.

Mr. GRANDY. Can you contrast that with the Waxman approach to the same problem?

Mr. BENBROOK. The Waxman approach shares many features, but it is much more complex an approach. The Waxman bill establishes a discrete quantitative standard of 10 to the minus 6, and it also has rather precise language on how that has to be calculated. It also makes reference to the most sensitive population group which will cause the agency to have to determine what part of the population might consume most of the food, or might be most susceptible. In most cases, that is going to be infants and children.

So, because the Waxman bill has many other features, both technical and procedural, it is difficult for me to contrast that. However, it is certainly possible that if all existing pesticides were brought simultaneously into compliance with the Waxman bill, you would also eliminate this old-versus-new bias.

My concern is, and the concern of many people who have studied both bills, is that while the two bills may allow EPA to go in much the same direction, the procedural difficulty of the Waxman bill may make it harder to get there.

There is a considerable history behind this concern. Mr. Brown has been through many oversight hearings about problems with the special review process, problems with market data from IBT. When serious problems arise, Congress has tended to pass a more complicated, procedurally encumbered process to try to force EPA to go in a given direction, but what happens is that EPA just gets bogged down because it is very difficult to do precisely what the legislation says.

I think that is the principal concern the Congress ought to have in evaluating a simple approach like the Roberts-Brown bill, versus a procedurally quite inflexible and complicated approach as reflected in the Waxman bill.

Mr. GRANDY. But, if I can just conclude, based on what you said earlier about the incongruities of the Delaney Clause in terms of zeroing in on what is dangerous and perhaps what is not, would you conclude that the Roberts-Brown is perhaps a safer vehicle when it is all tallied because you are moving to those areas of risk, perhaps, with more flexibility?

Mr. BENBROOK. I think that the Roberts-Brown bill is going to get the agency much quicker to a point where it can take action.

Now, whether it does so at that point is going to be a matter of the political will.

What is essential is that there has to be a consensus reached within the Congress on what the rules are, and the process for trying to unravel this problem. My biggest concern about the Waxman bill is that even if the Congress reached a judgment, consensus that that is the way to go, it might prove a very circuitous route to get to the ultimate objective.

Mr. GRANDY. Thank you, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Grandy.

Dr. Benbrook, I have no further questions for you. We appreciate your being here this morning.

Mr. Roberts has an additional question.

Mr. ROBERTS. Dr. Moore did testify at our last hearing that the science of risk assessment is very fluid, and if we were to embrace—

A rigid definition and descriptive approach I think we might be unwittingly substituting a new set of problems for the old set of problems that we find in regards to the rigid definition found in the Delaney Cause.

I know that there are those who will say that our approach is not sufficient for a regulator to fulfill the policy directives, i.e., public safety, at the EPA. And to answer that question, I suppose—and, as I pointed out, I feel the other approach simply is too complex, will lead to more problems than answers. So, to answer that question, I suppose I would like to ask you to describe whether the prevailing thought that you have stated here today on what is a risk that is very negligible, is it sufficiently thought out or, to be more accurate, will it be accepted by a majority of scientists and, more importantly, by the public?

And in this regard, perceived risk by the public in regards to what is in the national media, and I am not trying to perjure that one way or the other, and what is a real risk both short term and long term may be, you know, very different. I have an article here from a March publication, by a Mr. Mike Cummings, saying "Daring To Live," and he points out research respondents rank risks. He has a civic organization, college students, members of a business club, and then experts. You are in that latter category.

And they rank the top 30 risks to society. No. 1 by the college students and by the civic organization is nuclear power; No. 1 by the experts is motor vehicles, in terms of an immediate problem. Now I could go through the whole list here, everything from swimming and skiing and X-rays and even contraceptives, and we are going to leave that one alone this morning, and all of that, even power mowers. But you can see the perceived risk and then the actual risk. And Lord knows, we have tried to define the actual risk here with these many hearings as long as I can remember.

Are we ready to go to a negligible risk standard to get the kind of public acceptance necessary to back that kind of confidence? Is it possible?

Mr. BENBROOK. Mr. Roberts, you are very perceptive in noting that this is not going to be an easy road to travel regardless of what piece of legislation this Congress or the next one might craft in this area, or regardless of the guidance provided to the EPA and

regardless of whatever actions EPA might take. There is going to remain in our society considerable difference of opinion in terms of the willingness of people to accept involuntary risks, of which pesticide residues in food is clearly a principal example. So, the controversy is not going to evaporate under any circumstances.

However, to answer your question directly, yes, I think that it is possible for EPA to make and take regulatory actions based on a negligible risk standard that will command the confidence and respect of both the scientific community and the public. And, Mr. Roberts, they have done it. The current EPA in the last 6 or 8 years have taken a few such actions which appear to be inconsistent with the Delaney Clause, but they took them anyway and they published the basis of their judgment in the Federal Register, and people basically accepted it.

I think it is clear where the problem will arise. There are lots of instances where people will readily agree that the risks are clearly so small that one should not be worried about them. But in a few other instances, people will agree that risks are clearly great enough that something should be done; hence, EPA will take action to reduce risks or a company will voluntarily withdraw a registration of a pesticide. There have been examples of both. But in the middle—between clearly negligible and unarguably serious risks—there are going to remain certain instances where it becomes a matter of considerable scientific uncertainty about what the risks really are and hence, ultimately, a political judgment on how risk adverse regulatory agencies ought to be.

But I do think that there is a reasonably well defined notion of what negligible risk is amongst Federal regulatory agencies—not just pesticides, but OSHA and FDA and across the board—and the ability of EPA to defend such actions both in the court of public opinion and in courts of law. However, the debate is going to go on.

Mr. ROBERTS. One follow-up question, Mr. Chairman, and I will make it short.

Do we need a number in order to quantify and build that kind of confidence? And then I guess that depends on your point of view if, in fact, you are going to say that Diminicide should not be used on a crop like peanuts and point out the risk involved in extensive tests with laboratory animals, and that the risk is, as you say, 10 to the minus whatever it is. Some people might say yes, and some people might say no, I don't want to take that chance, and that we shouldn't take that chance.

A colleague of mine on the Tobacco and Peanuts Subcommittee did a little research and pointed out that the average human consumption to the degree that was fed to the laboratory animal, i.e., the lab rat, that an individual would have to eat 600 pounds of peanut butter a day in order to receive that kind—or that kind of level.

Now, if you pose it in that context why people are going to say, "Well, that's ridiculous and I'll keep on eating, you know, Peter Pan," and the schoolchildren of America will continue to eat their peanut butter sandwiches. And that is what worries me.

Do we need a number? I think numbers pose a greater problem than what we are trying to accomplish in the bill.

Mr. BENBROOK. Well, I think that as a practical matter there is such a degree of confluence, if you will, in the regulatory actions of different Federal agencies around a one in a million, or 10 to the minus 6 standard that that is sort of a generally accepted notion of a negligible risk level.

But I don't think that you have to specify in legislation what that number is. I think the regulatory agency is going to be bound by generally accepted public policy actions and legal precedents, and the views of the scientific community. It may tend to wiggle around between 10 to the minus 6 and 10 to the minus 4. It is in that range where it is going to be very difficult. But you picking 10 to the minus 5 isn't going to make it any easier.

Mr. ROBERTS. No. If you pick that, why somebody is going—you know, if you pick a number, somebody is going to say change the number.

Mr. BENBROOK. Yes.

Mr. ROBERTS. On both sides.

Mr. BENBROOK. Let me add one other thing. I know that it is reassuring to some to think of ridiculous examples of how much a person would have to eat to consume a dangerous amount of a pesticide. But I can tell you that as more and more actual residue data comes in, and as we look at dietary exposure to pesticides more realistically, the data will likely still lead to some instances where risks are well above a negligible level. This is why as more research is done, as EPA develops groundwater data and better tools, it is not going to make the problem go away. It will allow the agency to pinpoint where the problem is much more accurately, but still it will be there in some instances. And either the regulatory agencies are going to have to convince the public that that level of risk is acceptable, or steps will have to be taken to do something about it.

Mr. ROBERTS. But the bottom line is you get the bad actors out of there.

Mr. BENBROOK. That is right. And they are not going to go away by making comparisons to how much peanut butter you would have to eat to become ill, or receive the same dose fed to a rat in an animal experiment.

Mr. ROBERTS. I appreciate that. Thank you for your contribution, Chuck.

Mr. BENBROOK. Thank you.

Mr. BROWN. Chuck, before you leave, Mr. Stenholm has another question.

Mr. STENHOLM. Dr. Benbrook, can you recite or furnish for the record the occurrence rate of cancer over the last several years?

Mr. BENBROOK. The National Cancer Institute does an excellent report about every 5 years; it is kind of a statistical update of cancer trends, and they came out with one, I believe, earlier this summer or within the last year. Perhaps I could get the "Executive Summary" of that report and provide it for the record with the other material.

Mr. STENHOLM. I would like to include that information as an attachment to your testimony.

Mr. Roberts, you read the study that ranked nuclear power as the No. 1 threat.

It certainly would be my hope as a member of this committee that we could approach the subject of agricultural chemical utilization in a national manner. From a farmer's perspective, I do not know of a single producer that wants to continue to use any chemical that in fact is going to be injurious to himself, his family, his neighbors and those that will live on that farm after they leave.

We need to have a meeting of the minds between all parties that would like to lessen the dangers of pesticide contamination. However, we need to do so within the confines of common sense.

Mr. BROWN. Thank you very much, Mr. Stenholm. Thank you, Dr. Benbrook.

Our next witness is Dr. John McCarthy, director of scientific and regulatory affairs of the National Agricultural Chemicals Association.

STATEMENT OF JOHN F. MCCARTHY, DIRECTOR, SCIENTIFIC AFFAIRS, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ACCOMPANIED BY GEORGE L. ROLOFSON, MANAGER, GOVERNMENT RELATIONS, CIBA-GEIGY CORP.

Mr. MCCARTHY. Thank you, Mr. Chairman. Accompanying me here today is Dr. George Rolofson, from the Ciba-Geigy Corporation.

Mr. Chairman and members of the subcommittee, I am grateful for the opportunity to testify today on behalf of the National Agricultural Chemicals Association on H.R. 4937, the "Pesticide Food Safety Act of 1988."

I have a written statement which was submitted on July 28, which I request be entered into the record, and I will just summarize a few points here.

Mr. BROWN. Without objection, it will be in the record.

Mr. MCCARTHY. All members have a vital interest in this legislation and look forward to working with you and your subcommittee as it examines proposals to address the inconsistencies in EPA's legal authority in this area. Mr. Chairman, we must solve the inconsistency in our food safety laws. As the National Academy of Sciences reported in their report a year ago, it makes no sense to have a dual standard for raw and processed foods and for old and new pesticides which have been found to have an oncogenic response in laboratory animals.

From day one, we have consistently supported the basic recommendation contained in the NAS report: specifically, the concept of negligible risk applied across the board for raw and processed foods for both old and new pesticides where there is evidence of an oncogenic response in animal tests.

We have stressed, at the same time, the need for flexibility in the methodology for determining what constitutes a negligible risk. The process of risk assessment is complex. It is continuously evolving. New and improved methodology is appearing such that it would be a mistake to freeze the science through legislative action.

Mr. Chairman, the proposed legislation presented in title II provides not only a solution to the inconsistencies noted earlier, but provides the necessary flexibility to allow recent and future advances in the science of risk assessment to be applied to the regis-

tration of pesticides on food crops. The authors are to be applauded for their approach. It is not only sound legislative policy, but it demonstrates trust and confidence in the science and the regulatory agencies. Our bottom line is that we support title II.

Turning to other aspects of H.R. 4937, we support title I's straightforward and efficient treatment of pesticide reregistration. Here again the reregistration issue has been of concern to us. As you know, we have long supported legislation to speed up this process. We are concerned, however, about two aspects of the proposed provision. First the legislation should insure that EPA has been given sufficient resources to meet the deadlines. The time-limiting factor has been and will continue to be agency resources with respect to dealing with the reregistration issue.

Second, the proposal's use of a registration denial hearing to challenge reregistration actions creates procedural changes which will cause some problems to us both in our industry and to the whole agricultural situation. The amendment suggests a shift in the initial burden of proof from EPA to the registrants. This subtle but important change is magnified when registrants, agricultural users, company stockholders, lenders and many others are faced with literally hundreds of millions of dollars of potential losses if reregistration is denied. Farmers and ranchers depend on existing products and may find a few or no acceptable alternatives if EPA refuses to reregister the product.

We have provided language to the staff which will rectify the problem in this proposal.

We would like to close with just some brief comments on title III. Integrated pest management is a subject that we have supported for some time. We share your support for advancing IPM technology through continued research, and it is a common sense approach to pest control. We have long stated that pest control products should be used only when you need them. The days of "spraying by the calendar" are far behind us. If, indeed, there is need for a federally funded program to advance this, we certainly support that it be a coordinated effort. Too often programs such as this go on with no particular oversight or coordination. So we have no special problems with the creation of this oversight function in title III.

We thank you for this opportunity to testify on this important legislation, and we look forward to working with the subcommittee on this and other proposals needed to enhance public health protection and food production. We would be happy to answer any questions you have.

[The prepared statement of Mr. McCarthy appears at the conclusion of the hearing.]

Mr. BROWN. Thank you, Dr. McCarthy.

Did Dr. Rolofson have anything further to add?

Mr. ROLOFSON. No, sir.

Mr. BROWN. Mr. Roberts.

Mr. ROBERTS. I yield back at the present time to my learned colleague from Texas, who I know has some questions.

Mr. BROWN. Mr. Stenholm.

Mr. STENHOLM. Thank you, Mr. Chairman.

Dr. McCarthy, I need your help in clarifying several issues. In this whole issue of food safety and pesticide residues we are at-

tempting to deal with the presence of very low levels of pesticides that may have caused cancer in animal tests; is that correct?

Mr. McCARTHY. That is correct. Of course we are talking about low levels of pesticides that have a variety of biological effects, if you will, but the issue here today is with regard to the cancer issue and trying to fix the inconsistencies in the way we deal with that.

Mr. STENHOLM. In these animal studies that are utilized is it possible to distinguish between potent carcinogens and weak carcinogens?

Mr. McCARTHY. That is absolutely correct, that can be done. For example, something that may cause a cancer response in both rats and mice in animal tests at very low levels, one would say that is a potent carcinogen; and, as contrasted to something that may cause a tumor-induced response in one sex or one species at a very high level, then one would say that that is kind of a weak carcinogen. So that you get a whole spectrum of things. And this is recognized by experts and including the EPA, who has devised classification schemes for various carcinogens based upon the fact that they have different response factors.

Mr. STENHOLM. So as an important facet or part of the process, it is important to identify what kind of a carcinogen we are dealing with?

Mr. McCARTHY. That is absolutely critical to the whole aspect of risk assessment and carcinogens.

Mr. STENHOLM. Getting back to the question Mr. Roberts asked the previous witness, there is some talk of setting a specific level of risk; one in a million, for example, for carcinogens in food and even in drinking water. Should an acceptable or negligible risk depend on the kind of carcinogen you are talking about? Would it be advisable to establish numerical standards?

Mr. McCARTHY. Well, there are problems with setting a numerical number in legislation with regards to carcinogens. One is with regards to the nature of the carcinogen. Not all of these are amenable to this quantitative risk assessment that come up with a 10 to the minus whatever, and this is recognized by all experts who have dealt with that.

As a matter of fact, the EPA in their proposal to reexamine the cancer risk assessment guidelines are raising that question again as to when is it appropriate to do this mathematical treatment of these cancer data. It is not always appropriate to do that. So that if one fixes a particular number in a piece of legislation it kind of locks you in to run all of these carcinogens whether they are weak or they are strong through this mathematical drill, and that is not necessarily relevant or appropriate.

The other thing that I would like to share with you in regards to the number situation, when I have talked to people who have had to deal with this in California with regards to Proposition 65, they have had to deal with—the Science Advisory Panel has had to deal with the no significant risk issue. When I have asked a number of those people who have served in that capacity would they have liked to have had a fixed number in that legislation the answer is absolutely not, because of the nature of the science. Somebody's number is 10 to the minus 6, somebody's number is 10 to the minus 4, or somebody's number is 10 to the minus 5—so there is that

issue. And then there is the issue of well not all carcinogens is it relevant to run them through this mathematical process.

So it is the weight of the evidence and it is an informed judgment. At some point there are some carcinogens where you are going to have to pick a number and say well that is the level of risk for this particular one because it makes sense to do it that way.

That is a very long-winded answer but that kind of shows you where we are in this process of risk assessment and animal cancer studies.

Mr. STENHOLM. So, to sum up, you are saying it is extremely important to understand that not all carcinogens are the same.

Mr. McCARTHY. Exactly.

Mr. STENHOLM. Should a level of risk be established on a product-by-product basis?

Mr. McCARTHY. Yes.

Mr. STENHOLM. Thank you, Mr. Chairman.

Mr. BROWN. Mr. Roberts.

Mr. ROBERTS. Yes, Mr. Chairman.

On page 3 of your testimony you express considerable concern about the proposal as to use of a registration denial hearing to challenge reregistration actions, and I note that concern is mirrored about 180 degrees' worth with some witnesses that will follow.

Would you amplify on that from the standpoint of your company's perspective?

Mr. McCARTHY. I would like to throw the ball to Dr. Rolofson on that.

Mr. ROLOFSON. Congressman, I think our concern on that is that the process as it is described could essentially take a product off the market for a reason that would not hold up over the long haul. And it is the lack of continuity that concerns us there. The reregistration process as it is defined is supposed to click in every 5 years, and we think the process is so stringent to begin with and the data requirements these days are so firm and hard that to make it relatively easy to not continue the registration of a product has some serious disadvantages to not only the long range planning of our business, but also to the long-range availability and the continuity there for our customers.

Mr. ROBERTS. I think it is ironic, Mr. Chairman, that as we try to get this laundry washed through this new process to the satisfaction of agriculture and industry and the environmental community that it is obvious we have some concerns expressed by the current panel about the uncertainty that the process would cause; and yet, on the other side of it, we have concerns by others who want a time cycle on the wash, and in the meantime we don't get anything washed.

Mr. ROLOFSON. I think our concern is not that we can't address major scientific risk questions that come up after we are on the market, and looking at the data bases that we have to provide these days, we think we can address those if we are given time. But to make a product's life on the market end prematurely because questions have been raised and time has not been allowed to answer, we see that as the direction this could go and we think

that it would leave us with a lot of uncertainty that would make it very difficult.

Mr. ROBERTS. I would like to get this worked out. We have a term called "sufficient time," if you will. I don't want to be put in the role of the arbiter as to what is sufficient time, but obviously there are people who feel that it is not defined well enough, and obviously you have a concern in terms of your products and the availability of such to farmers and ranchers and consumers that that would not be fair.

Let me move to another subject. What is going to happen if in fact we do not proceed with this kind of legislation of some type over the short term on the availability of pesticides for a very troubled and hungry world over the next 10 to 15 years? If we don't do something with the Delaney Clause, what is going to happen in 10 to 15 years?

Mr. ROLOFSON. I don't know if I have got that kind of a crystal ball, but what is going to happen is there is just going to be a lot of chaos that is going to go on. There is going to be a lot of lawsuits. EPA is going to be dragged into court because they haven't taken action on old pesticides which triggered the Delaney clause. If they go ahead and they implement the NAS plan without a legislative fix and approve this hops product, like Dr. Benbrook said, they are going to get hauled into court because they violated the Delaney clause. And it is going to be just a tremendous waste of energy and resources to deal with that, and I don't think we have to.

I can't, Congressman, answer your question of what it is going to do to the availability of pesticides. I think one way to look at it is from—and this is a little bit off the subject, but I am going to say it anyway. If one wanted to deal with it the way it is being proposed to be dealt with in the Waxman bill, all one has to do is to go to the NAS Delaney report, open up the book to the page where they have got the table of the risk numbers, and you just look down there and say, well, that has already been done because they did it by the prescriptions in the Waxman legislation, and all of those products would be gone.

Mr. ROBERTS. Give me a perspective, if you will, from the standpoint of a research and development director of a pesticide company who is obviously extremely concerned and frustrated in trying to bring on new products that are, hopefully, sound from an environmental standpoint, they don't leach, low toxicity? What kind of a problem does this pose for you?

I know there are people who say we don't want the fox in the chicken coop, and I don't want to put that banner around you. But it has always been amazing to me why somebody would think that somebody in your position would want to come out with a product that is unsafe. I don't understand that, not only from the profitability standpoint but just, you know, from a moral standpoint.

But, if you are in the business of trying to bring to fruition a new generation of less toxic pesticides, what does the Delaney Clause—you know, what do you do if you are a research director? What do you tell your CEO? Or your customers?

Mr. ROLOFSON. Congressman, one of the facts that is overlooked in this process, part of the testing procedure we go through in determining the carcinogenic activity of a product, we are required to

test at levels that have an effect. If we do a 2-year study and take another 2 years to look at the pathology and come up without an effect in that study, it is not a valid study. We have to have made the animal sick but don't kill them. In driving that high dose, we are overriding naturally existing mechanisms in these animals that they have inherited over history to handle foreign materials, to metabolize, to excrete, and to otherwise deal with foreign materials at low levels.

So that the testing regime that we are required to use drives us to forcing chemicals, many of them, to cause tumors when it would never occur at levels that we would see humans exposed to. This sets us into the Delaney dilemma because we now have a carcinogen. A lot of that data that is so derived does not fit the elegant mathematical models that are used to predict if that occurrence will happen at very low levels that man are exposed to. The models were not derived to use certain kinds of data.

Now, if that data is used anyway in those models, we come up with a risk level of one in a million. But it will give you a number. It doesn't matter whether the data fits the model or not, it will give you a number. Then the question is can we use that chemical in the farming practices today? Will it show up in food or will it show up in ground water at less than that one in a million number that may not be meaningful anyway?

So the dilemma our research directors are caught in is having to force the animals to survive these massive doses and then trying to put those data into some meaningful perspective. We are caught in the middle.

Mr. MCCARTHY. There is about a 30 percent chance—30 to 50 percent chance the way we test chemicals today that they are going to invoke some kind of a tumor response in a rat or a mouse just by the way we test them, and that is just the way it is going to come out. So research directors are confronted with that probability, and as we find "safer and safer" products, the acute toxicity, that is going to go up because you have to feed higher because the animals don't get sick until you get very high doses.

And the other thing that it does is that with that probability in mind that you are out there doing a lot of extra work with because if it does show up to be a tumor-producing agent down the line 3 years hence that you have got to do a lot of backup and duplicative and triplicative work to avoid food additive tolerances because that is where the Delaney Clause kicks in. And so again, it is a tremendous waste of resources to try to play the game.

Mr. ROLOFSON. We support your bill in that it doesn't set a number. The idea of relative risk in our society these days is a very important one that needs to be brought forward to the public. Our society has made the decision that chlorinating water, for example, is a good thing to do. In that process we end up with a by-product of chloroform, which is a carcinogen, and we have determined that a risk of 1 in 10,000, or 1 times 10 to the minus 4, is acceptable.

I think if our public would understand that it would be helpful in putting together a relative risk concept that would put a lot of minds at ease.

Mr. ROBERTS. I thank you for your testimony.

I have no further questions, Mr. Chairman.

Mr. BROWN. Mr. Stenholm.

Mr. STENHOLM. One additional question, Mr. Chairman.

On August 11, 1988, Dr. Rolofson, your company Ciba-Geigy, sent a letter to retailers in which you announced that you are removing Mylogard, a product brand name, from the market. You state that it is not related to any health or environmental concerns but it is due to reregistration costs. This is a product that has been utilized successfully by a lot of farmers, including myself, for years. I wish you would comment on that.

Mr. ROLOFSON. Mylogard has been on the market many years and it was one of those that was originally registered many years ago when the decision point on whether you provided carcinogenicity data or not depended on the residue that showed up in the crop. If it was a negligible residue, and that was less than a tenth of a part per million, you did not have to provide long-term studies. If it was greater than a tenth of a part per million, you did have to.

The use of Mylogard was a very minor crop area compared to major crops in the United States. It was used on sandy soils in West Texas, perhaps some in Kansas. It was not a big market. And when we looked at the cost of doing all of the new studies that it would take to keep that on the market, the long-range cost did not justify continuation of the product. So we chose to drop it and not reregister it.

Mr. STENHOLM. No further questions, Mr. Chairman. Thank you.

Mr. BROWN. Thank you very much, gentlemen, for your excellent contribution.

Our next witness is Mr. Stephen G. Lodge, Assistant Director for Legislative Affairs of the National Food Processors Association, accompanied by Mr. Clausen Ely, of Covington & Burling.

We welcome you, gentlemen, and you may proceed with your statement in any way that you wish.

STATEMENT OF STEPHEN G. LODGE, ASSISTANT DIRECTOR, LEGISLATIVE AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION, ACCOMPANIED BY CLAUSEN ELY, COUNSEL, COVINGTON & BURLING

Mr. LODGE. Thank you, Mr. Chairman. Good morning, Mr. Chairman and members of the committee. My name is Stephen G. Lodge, and I am the assistant director of legislative affairs for the National Food Processors Association. With me is Mr. Clausen Ely of Covington & Burling, counsel to the association.

We appreciate the opportunity to appear today, and I ask that you keep in mind the fact that we will be continuing to refine our position on H.R. 4937 as we hear more comments from our membership. The National Food Processors Association represents some 600 companies across the country including most of the major food processing firms. Most of our members are involved with the processing of fruits, vegetables, meats, fish and specialty products, and other members are involved in the manufacture of processing and packaging equipment and supplies.

Before presenting our comments on H.R. 4937, I would like to point out that research conducted by our laboratories and others have shown that most pesticide residues that may be present in or

on raw agricultural products are removed during food processing operations. Thus, the vast majority of processed foods actually consumed contain residues far below the levels that may be found on raw agricultural products.

Turning to H.R. 4937, the following provisions of the measure are particularly important to NFPA. We are pleased that H.R. 4937 embodies a negligible risk standard for setting pesticide residue tolerances and provides for continued consideration of benefits in setting those pesticide tolerances.

We are also pleased that the bill provides EPA with sufficient flexibility to determine specific levels associated with a negligible risk based on evolving scientific data and principles.

We also support the principle embodied in this bill that the regulation of pesticide residues should be consistent for both fresh and processed foods. H.R. 4937 would accomplish this objective by regulating all foods under section 408 of the Food, Drug and Cosmetic Act. Importantly, the bill provides that all processed foods for which a tolerance has not been established would have the same tolerance as that established for the raw agricultural commodity unless EPA determined that a higher tolerance was necessary and such a higher tolerance was in place.

Another important provision in the bill would require the use of actual pesticide use and residue data to the greatest extent possible when evaluating the relative risks of pesticide chemicals. The National Academy of Sciences, Delaney Paradox report is based on the erroneous assumption that all registered pesticides are used at the maximum application level and that they are present at the maximum residue level authorized by a tolerance. The use of real world pesticide use and residue data in risk assessments will result in more accurate and meaningful exposure assessments.

While we wholeheartedly support the above aspects of the bill, we believe that additional consideration should be given to the following issues:

We recommend that the bill be amended to provide clear authority for the FDA to be able to issue action levels for pesticides that are present in the environment from past use and which unavoidably result in residues in or on raw agricultural commodities and processed foods.

We also recommend that the bill be amended to provide that when EPA issues a final tolerance or the FDA issues a final action level that those rules become uniform across the country and should not be altered by State, county or local governments. If a State, county or local government has information that the established tolerances or action levels are not protective of public health, then they should offer that information to the EPA or FDA officials for their review and consideration, preferably during the tolerance-setting process.

The food industry needs a national system of uniform pesticide tolerances and action levels to effectively and efficiently market its products. We recommend that aspects of the bill concerning the registration and reregistration of pesticides be considered in the overall context of the reauthorization of FIFRA. The amendments to the Food, Drug and Cosmetic Act proposed in H.R. 4937 are important and deserve consideration on their own merits.

Lastly, we support the need for vigorous enforcement of pesticide laws on both domestic and foreign producers. If U.S.-based firms are forced to comply with stricter standards than are their international competitors, they will be placed at a serious economic disadvantage. We ask that you keep this potential problem in mind as you work on this and other legislation in the pesticide area.

As we stated at the outset of our statement, we will continue working with our members to further develop and refine our views and positions on this bill. We will keep you informed if any of our policies or positions change as a result of our continuing discussions with our members. We appreciate this opportunity to present our comments and would be pleased to respond to any questions.

[The prepared statement of Mr. Lodge appears at the conclusion of the hearing.]

Mr. BROWN. Thank you very much, Mr. Lodge.

Mr. Roberts.

Mr. ROBERTS. Mr. Chairman, I have a little blood pressure on another issue that may or may not be related, and since Mr. Lodge is here and he is handy I am going to bring it up now and ask if I might later, after Mr. Stenholm and yourself are through conducting your questions, return to maybe one or two pertinent to this bill.

Steve, do you recall the Poltergeist movies with a little girl in front of the television turns around and the room shakes and the TV is like this and there is all sorts of tremors and she says, "They're back"?

Mr. LODGE. Yes, I do.

Mr. ROBERTS. In the seventies, we had a whole host of consumer activist initiatives involving beef, price freezes and embargoes and boycotts and market manipulation, et cetera, et cetera, when allegedly we got into short supply of our commodities and the farmer's price i.e. allegedly got too high, i.e. we are going to run short and the consumers are going to pay more for their food product.

Well, guess what. After a decade of trauma and pain and suffering, with prices far below the cost of production, we have now seen an increase in price due to the drought—if, in fact, the farmer has any crop to sell—and they're back. It's consumer poltergeist again. These consumer organizations have urged the Secretary of Agriculture to stop the Export Enhancement Program, which has got our supply-demand balance about where we are going to maybe get back the cost of production in farm country after 10 years and after \$26 billion of taxpayer money. As you can tell, I have a little feeling about this. Now, we have here the consumer organizations saying, "Because of the drought we are going to be in this situation, and, Dick Lyng, you should stop that Export Enhancement Program, shouldn't be using it."

Now you represent "600 companies across the country including most of the major food processing firms. Most of our members are involved with the processing of fruits, vegetables, meats, fish, specialty products," et cetera, et cetera. And most of the editorials in my country are saying that the consumer organizations' efforts are misdirected, "It's that nasty old middleman," i.e., the food processor, who is guilty of passing this cost on and then some to the consumer. It is going to cost the consumer an average of \$1.46 for the

whole dadgum year for the increase in the dollar to his wheat price, from about \$2.50 to \$3.50. And I think my figures are right, where we have 146 extra loads of bread for every family of four in this country over and above what we normally use. We have the grain. We have the supplies. We need to continue that export program. Finally get the profit back.

After my long-winded speech—are you the folks really responsible for this business of gouging the consumer? And I think it is time that your Association spoke to that and pointed out the facts as you see it or we are going to go back down that road to ill-advised consumer actions that are very contrary to the best interest of agriculture and, in the long term, the consumer. Would you care to speak to that?

Mr. LODGE. I can only speak to the fact that we are not in a position to comment on the prices at this time, I think resulting from back in the days of wage-and-price controls, because it would have some affect on prices down the road. So I am afraid I cannot speak to that myself, but I would be more than happy to try to get some kind of official response for the record from the association because there may be some in the meantime.

Mr. ROBERTS. Well, I am not asking for an official response in regards to our subcommittee jurisdiction over this particular bill on this subject. I am just advising you that there is a ruckus out there now in regards to food prices that I think is very ill-advised in direct relation to the supply of our farm commodities and the price the farmer is receiving, and I think it is in your best interest as would be—what, the grocery manufacturers, et cetera—to speak to this issue. And, in fact, if you have got a good case to make, make it.

Mr. LODGE. OK. Thank you.

Mr. ROBERTS. But I sure don't want to go back down that road to consumer interference—well, that is not what I want to say—ill-advised policy being advised by understandable concern on the part of our consumer organizations that would be very counterproductive just at the time we are trying to get some profit back to agriculture. It just seems to me that is just unbelievable at this particular point.

And I thank the chairman's indulgence on that issue.

Mr. BROWN. Thank you, Mr. Roberts.

Mr. Stenholm.

Mr. STENHOLM. Mr. Lodge, would you comment a little further on your recommendations where the bill before us could be improved? Should FDA be provided clear authority to issue action levels for levels of pesticide residues? Should there be statutory requirements for tolerances to be uniform across the country?

Mr. LODGE. On the action levels there apparently seems to be some confusion as to whether FDA has the proper authority to issue in a quick fashion some kind of rulings on pesticides that inadvertently land on food from environmental pesticide use. And I think to answer that question more specifically, maybe Mr. Ely would be able to do that.

Mr. ELY. Yes. As we understand it, historically FDA has used section 406 of the Food and Drug Act to set action levels for unavoidable environmental pesticides that contaminate foods but are

not applied to the food. The way this bill is written it would seem to put all regulation of pesticide residues under section 408 and require that a tolerance be established for any residues under that section, and we were concerned that EPA would have to issue tolerances and go through that relatively elaborate procedure to set levels for unavoidable environmental pesticide contaminants. We wanted to make sure that the bill provided EPA or FDA continued ability to set action levels for these unavoidable contaminants.

Mr. LODGE. As far as the FIFRA aspect that you were mentioning, it is basically a matter of these issues being very important to us. With the Food, Drug and Cosmetic Act and the negligible risk, we just feel that it could get lost in the shuffle if it is considered along with the FIFRA issues. But, you know, we are supportive of many of the aspects of the FIFRA portions of the legislation, but feel that that applies more to pesticide companies, say, than to the food industry itself. That is why we are more concerned to just have that considered along with FIFRA.

Mr. STENHOLM. Do you support uniform tolerances to be applied nationwide?

Mr. LODGE. We are strongly supportive of uniformity across the country and have been working with some of the committee staff people to perhaps have that put back into, if it is at all possible, the legislation that is being considered in this committee and in Energy and Commerce because we feel it is vital to the well-being of—interstate commerce makes it very difficult to deal with 50 different tolerances from each of the different States. So we are strongly supportive of the State and local governments participating in the tolerance-setting process from the very beginning. If there are any kind of problems that they have, they should make them known to EPA when the tolerance is being set.

We are happy to abide by the tolerances, to pesticide tolerances, but if there are 50 different ones it makes it extremely difficult. And we also feel that the Federal Government has the proper experience and expertise to deal with this problem and weigh all the factors most appropriately as opposed to having each of the State governments involved.

Mr. ROBERTS. Would the gentleman yield on that point?

Mr. STENHOLM. I would be happy to yield.

Mr. ROBERTS. As the coauthor of that provision, let me point out also it has been referred to as States rights. And, obviously, if the States of Massachusetts and California, or for that matter Kansas, wanted to set a stricter standard on behalf of public safety they should have the right to do it. Mr. Stenholm and I have indicated that is probably more like State fights rather than State rights, and the whole point being from a public safety standpoint you may well feel that EPA is not doing the job and you may well feel that the Commonwealth of Massachusetts or California or the sovereign State of Kansas could do a better job. But if it is not safe in Massachusetts or California, why on earth should we expose our consumers to something that is not safe in Kansas? I mean, there is a public safety question there as well.

And I would agree that there are some areas of concern that I have in regards to alleged—what?—foot-dragging on the part of the EPA, but we ought to make the standard, once we get it reformed,

uniform across the way because we have a Nation's food supply, not an individual Massachusetts food supply, or California, or Kansas, or Texas.

And I thank the gentleman for yielding.

Mr. LODGE. I agree completely.

Mr. STENHOLM. Is there a reason why you would suggest that the legislation before us omit pesticide reregistration and yet include uniform tolerances?

Mr. LODGE. We will be trying to address this issue during the FIFRA consideration, and also if the Energy and Commerce Committee moves on the Waxman measure.

Mr. ELY. If I might comment, I think one reason is that tolerance uniformity, obviously, has a lot to do with 408 which sets tolerances and is a critical element of that. While NFPA supports the concept of some additional reregistration authority, it is evident from the testimony this morning that there is some disagreement about how that authority ought to be fashioned, which might bog down this bill and might equally be considered with the FIFRA legislation.

Mr. STENHOLM. Thank you very much.

Mr. BROWN. Do you have any questions, Mr. Morrison?

Mr. MORRISON. No.

Mr. BROWN. Gentlemen, I have no further questions. So we thank you again for your testimony this morning, and we expect we will be hearing further from you.

Next witness is Ms. Maureen Hinkle, director for agricultural policy of the National Audubon Society.

We welcome you here this morning, Ms. Hinkle, and you may proceed with your statement.

**STATEMENT OF MAUREEN KUWANO HINKLE, DIRECTOR,
AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY**

Ms. HINKLE. Thank you, Mr. Chairman, and members of the subcommittee. The National Audubon Society appreciates this opportunity to testify on H.R. 4937, the Pesticide Food Safety Act of 1988.

Your attention to the food safety issue is timely. As you know, recent national polls find that an overwhelming majority of the American public do view pesticide residues as a serious health hazard. Therefore, your efforts to bring together aspects of the National Academy of Sciences report criticizing EPA's tolerance-setting process and new initiatives for integrated pest management are, in our view, appropriate.

However, it is unclear how H.R. 4937 would immediately or very soon reduce the load of carcinogens now in our food supply when it would provide registrants with 12 years to put together a complete data set for each untested chemical, require rapid review by EPA once application is submitted, allow indefinite time for data gaps to be filled, and fail to provide a fee structure to pay for this quick review.

Moreover, H.R. 4937 provides for use of existing stocks of cancelled pesticides when we think that such stocks should be recalled and disposed of as a hazardous waste. Title I would mandate EPA

to review data expeditiously but no longer than one year after date of submission of a complete application for reregistration. No provision for fees to recover the cost of this fast-track new registration is provided, thus implementation would amount to automatic reregistration.

While proposing a stringent 1-year action frame for EPA evaluation, it would require EPA to allow registrants sufficient time to obtain any requested additional information. Registrants may keep products on the market for whatever time it takes to comply with requests for data.

In regard to title II, Audubon believes that the presence of carcinogens in our food and water should not be accepted as inevitable or necessary. The fact that carcinogens are in our food and water supplies does not mean that they should be legally sanctioned as negligible or acceptable. We support negligible risk only under carefully prescribed circumstances with specific limits and criteria, and only if negligible risk actually reduces the load of carcinogens in food and water and eventually helps to bring the total aggregate of carcinogenic pesticides down to a negligible risk.

Unfortunately, the provision for negligible risk provided in H.R. 4937 is vague, ambiguous and open-ended. To establish a protective and defensible negligible risk standard, dietary exposure to a pesticide chemical or a pesticide chemical residue must include other known sources of dietary exposure such as drinking water and consideration for health risks of identifiable population groups that may suffer higher than an average risk such as the old and/or chronically ill.

We are pleased that title III is devoted to integrated pest management. IPM and low-input technologies can surely help to reduce the quantities of pesticides used on crops, and therefore lower residues on food. Institutional incentives increase the quantities of pesticides now applied on each acre each year simply to increase yields. Today's high input costs, low market prices and pesticide contamination of food and water supplies demand that we act to reduce inputs and the incentives to apply more of these agricultural chemicals.

We are encouraged with the provision for extending coverage under the Federal Crop Insurance Program to cover pest losses suffered by farmers employing recommended IPM techniques. This is the type of encouragement that is needed to bring about more IPM advisers and more subscribers to IPM programs. At the same time, we would like to know why the new IPM initiative is limited to minor crops. What is the criteria for minor versus major crops? Apples and citrus constitute a large proportion of the average daily diet as well as acres in production, and they are considered major crops. We agree that minor crops are neglected, but we believe that IPM funds should be available for major crops also.

If carcinogenic pesticides are to be used in an IPM program, there should be a plan where use is prescribed by trained and responsible experts, and monitoring, integrated into the plan to assure the public that residues do not exceed specified levels.

Mr. Chairman and members of the subcommittee, the risk from the substantial number of pesticides posing a carcinogenic threat in our food and water supplies is, as we said before, unacceptable.

There is a clear and compelling need for procedures to reduce progressively this risk, and while H.R. 4937 has parts of such procedures it does not create a system, a comprehensive system, to accomplish a progressive reduction of carcinogenic pesticide residues in food, to remedy the delay in filling the data gaps which exist in over half the pesticides now in our food, or to provide sorely needed agency resources. However, you have addressed new issues such as the coordinating committee to examine minor uses of pesticide and IPM.

I would like to take the opportunity to comment that I think the critical problem with EPA and why it has not been able to address the problem of tolerances and reregistration has not really been leadership. It has been the resources that have been cut each year while their program gets more and more backlogged. I just wanted to answer a question that I wanted to pose to myself.

Thank you.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Mr. BROWN. We appreciate that comment about the importance of resources. I think we have recognized that that is a key element in any effort to get EPA to exercise more leadership. They have to have resources to do it with.

Mr. Roberts.

Mr. ROBERTS. Yes, Mr. Chairman. I want to thank the witness for coming and thank her for her long-standing efforts to achieve some kind of bipartisan support for some answers in this whole area. She has been most helpful to me and my staff and most willing to work with us, even though on occasion we have a minor difference of opinion. Certainly not in the goal, but in regards to the path that we get there from here.

And I agree with you on the funding, and I would point out that there is at least some chance for a FIFRA bill; i.e., the Lugar draft, if, in fact, that is the title that we now put on this. A pared down bill, if you will. And part of the accepted compromise is a revised fee structure on the part of the companies that will, in fact, answer at least a part of the problem that you are referring to.

And as I have indicated in many hearings, we are very good at, you know, holding hearings and discussing the problem, and we mandate the results, but we are not very good in terms of funding the appropriate agency to do the job. And so I think you have made a very pertinent comment.

I would simply like to ask a couple of questions, and I will take one that is rather controversial right off the bat.

Page 3, Maureen, you have indicated,

If a pesticide is dangerous enough to constitute an imminent health threat, it is too dangerous to be allowed to make its way through the channels of trade. Such stocks should be recalled and disposed of as hazardous waste.

Now, obviously, that is subject to opinion as to whether or not the pesticide does actually constitute a risk to that degree, but let us say that it does.

I was very interested in the testimony of several years ago by a producer-farmer from Garden City, Kansas, in my district, who was referring to Dynaseb, as I recall, and if in fact that product were

cancelled, and there are those who think it should be cancelled, that there was no practical way for the farmer on an individual basis to get this into a category of hazardous waste and, more importantly, to dispose of it. And that if he did not under a certain time period, then he falls under RCRA, which is another set of hurdles in statute, and then he is liable. And he went into a rather lengthy process and detailed questioning by the chairman and myself of what do you do with this. Do you report it? And if you report it and you can't get rid of it, i.e., you can't haul it, you can't package it, where are you going to ship it? We don't have the means to dispose of it. You know, who is going to dispose of it?

And more often than not, with the cost incurred, you know, where he has the product, several things could happen, and we have seen it happen. You get into a storage site but we really don't have the ways and means that are permissible to dispose of it, and so it constitutes even a worse hazard in terms of a storage site and you get into leakage, whatever. If you have an accident on the highways or something of this nature, you really got a problem. And so the farmer is sort of stuck with this as opposed to the pipeline provision and maybe providing, using this substance in much less amounts, you know, if you will.

He may store it on his own property. Worst case scenario, he may put it in the ditch and simply cover it up and, you know, hope like heck that nobody remembers that he has the product, which means it would then leach into the groundwater, and that would be the worst of all possible cases. Or he may simply just what? I guess keep his mouth shut and use the product.

I am not at odds with the need for a cancelled product to be taken off the market and to protect the public. From a practical standpoint, how on earth do we do this?

Ms. HINKLE. That has been one of the big questions in FIFRA ever since the 1972 amendments passed, and section 19 has remained basically untouched. It has left it up to the farmer to store and dispose of his pesticides as he saw fit, basically. He could even bury up to, I think it was 50 pounds or one day's use on his own land to get rid of the pesticides.

I made that point basically because even though it is now an option for EPA to allow excess stocks to be used up wherever they may be, we do not believe this is safe for the farmer to do. Because some farmers, knowing they can use their pesticides, are tempted to stockpile and then use it for the purposes they have always used the pesticide for. Aldrin/dieldrin is a pesticide that was used in that way.

Mr. ROBERTS. Some in Texas have done that. I don't know any in Kansas who would ever do anything like that.

Ms. HINKLE. I hope not for your sake.

In any case, we believe that section 19 does need to be taken care of, and we are very happy that you did seek to address that in a subcommittee markup. And we would hope that you could bring Congressman Synar's concerns on this issue, which I share, which Audubon shares, as you go into full committee markup. It is one of the big black holes of FIFRA. It stands out as a problem that needs to be addressed now, as the public gets more concerned not only

with pesticide disposal but disposal of all of the wastes that we keep producing at a rate faster than we know what to do with.

Mr. ROBERTS. Well, I thank you for your response.

Mr. Chairman, in anticipation of the statements that have been made by Ms. Hinkle, and also by Ms. Hathaway, who will follow as the next witness, I do want to make three very quick points.

There is concern on the part of both organizations, and others, that the bill we have cosponsored really provides little in the way of any reduction of risk, and I guess that really gets into the interpretation of what the bill would involve. I just want to state for the record that if I didn't think this would result in some very pragmatic and real risk reduction I wouldn't have introduced it.

On page 11 of the bill we do track existing language, in section 8, very closely with a notable increase in stringency by stating,

* * * tolerance shall not be established or left in effect above a level that the Administrator deems to be associated with a negligible risk to human health, except as otherwise provided * * *.

Now it is not numerically stated, I understand that. But I do believe the concept is sufficiently well-developed and understood that significant risk reduction is certain and yet what we are trying to do is provide the regulatory flexibility in an environment of very fluid science. I know we have disagreement on that, but I think the goals are certainly in common.

Second, I know that you have some concern about these exceptions being too broad. We have three exceptions to that standard. First, if there is clear and convincing evidence that the benefits to consumers associated with such a tolerance in terms of an adequate, wholesome and economical food supply outweigh the risks. Now here is the paradox, Mr. Chairman. We insisted on putting that in there and stressing consumers to rebut the complaint that we knew would be forthcoming that benefits are always considered in terms of the pesticide company and the farmer. So we put consumer in and then find that some of the criticism coming back on the bill is, in fact, that section; and that shows you, you know, some of the problems that we get into.

Second, the tolerance greater than this so-called negligible risk may be permissible if they replace a relatively riskier pesticide for the same crop. I think that is self-explanatory.

And then third, when the Administrator determines that substantial risk reduction to humans and the environment can be achieved under FIFRA. Now, if the real problem is due to groundwater or worker exposure, which we have had a lot of publicity on here in the last several weeks in the Southwest and the Far West, or an endangered species, hopefully, by doing those kinds of things you can protect the public and then that tolerance would not be necessary, at least at that level on that pesticide.

And then another concern, and this is the last one, Mr. Chairman—and I apologize to my colleagues in going overtime—your bill makes no improvement of really monitoring the pesticide residues. I think FDA has the needed authority. And as a matter of fact, they have now issued a draft report to substantially expand its whole program of monitoring, and I know many agencies issue task forces and reports and draft reports and final reports and what-

ever, but I am going to be offering them my comments very shortly and hope that we can expedite that all process.

So I think there areas in which we can work, and I think there are areas that, hopefully, we can achieve some progress. And I thank you for your contribution.

Mr. BROWN. Do you want a rebuttal, Ms. Hinkle?

Ms. HINKLE. Well spoken.

Mr. BROWN. Mr. Stenholm.

Mr. STENHOLM. Ms. Hinkle, where you state:

* * * if a pesticide is dangerous enough to constitute an imminent health threat it is too dangerous to be allowed to make its way through the channels of trade. Such stocks should be recalled and disposed of as a hazardous waste * * *.

I totally agree with you on that statement.

My question to you is, in disposing of it as a hazardous waste, what do you and your members propose in the way of a standard for disposal? Is it the same standard that you are testifying today whereby there is no risk acceptable? Would a method of disposal that would eliminate 95, 96, 97, or 98.5 percent of the hazardous chemical be acceptable to you?

Ms. HINKLE. In the case of 2,4,5-T, or agent orange, when the stocks needed to be disposed of, the incineration efficiency was 99.999999, and we judged that to be sufficient. In regard to most of the stocks of suspended pesticides that would be recalled from the company, and this has been done by companies—Ciba-Geigy did it in regard to chlordimeform. They recalled every single drop through the retail level down to every last farmer who had it. They are capable of recalling through the distribution channels, and the registrant is in the best position to know how to dispose of this chemical that they have produced. They knew how to produce it, they know what chemical changes occur at any given point, and I think that they should be given the responsibility to either recycle, reuse or manufacture it into some other form. But it should be given back to the company, and this way we might curb some of the tendency to just produce because someone will take care of it or it will be so disseminated that it will not be detectable.

And I feel we have to make people more responsible for their actions. That includes environmentalists and consumers, too.

Mr. STENHOLM. As chairman of the Small Business Subcommittee on Energy and the Environment in which we held hearings, whereby numerous small businesses had developed the wherewithal to literally destroy 99.0 percent of these hazardous wastes that we talk about, but because of the liability question were unable to utilize various disposal methods.

In all due respect, Ms. Hinkle, you and your association's continued unwillingness to accept any level of tolerance for pesticides has not been based on the best of science. We currently have numerous techniques to dispose of chemical wastes of all shapes and forms, but because of the inability to get approval out of EPA and FDA due to liability, the methods can't be marketed.

I say this in all due respect to your association because I share Mr. Roberts' opening comments. But, if we are going to pursue this subject, there is going to have to be what we call in Texas "West Texas tractor seat common sense" approaches to it. From a govern-

mental standpoint, it can't be perfect and ever get there because of the "sue the heck out of whoever it is that fouls up whatever it is" attitude we have got in the United States today. The liability question alone is keeping the techniques away from the market. Many techniques which are unavailable commercially will allow us to do a much better job of removing from the environment those things that all of us can agree should be removed.

If, in fact, we agree that a product should be removed and we have got the technology to destroy 99.5 percent of a product, we cannot get it approved because of the continued demand by others that it be 100 percent? Any comment?

Ms. HINKLE. I am not aware of who is making the 100-percent requirement. However, I felt that my testimony was fairly common sense and reasonable, and I regret if it conveyed that I was asking for perfection. I was careful in trying to avoid any such trap.

Mr. STENHOLM. I will accept that if I misread it. Thank you.

Mr. BROWN. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

I wanted to explore just one part of your statement. I have been extremely interested in the arena of negligible risk and I think this bill and the work of the National Academy of Sciences and others moves us in that direction, and I am glad to see you as an active participant because your reputation precedes you.

One of your statements say you support negligible risk under carefully prescribed circumstances, and certainly no one can argue that. Then you say, and only if negligible risk actually reduces the load of carcinogens in food and water.

My question is do you dismiss out of hand the possibility that current levels of carcinogens might reflect negligible risk? You seem to be insisting that you reduce this burden, and yet it has not gone through the test of determining whether that is negligible or not.

Ms. HINKLE. Actually, if you look at the Academy charts and look at the various risk levels, it still is only looking at residues on food, and I think we have to look at other sources.

The reason that we have even arrived at this point is that we do have a problem. There is a problem that is now widely recognized, and the question now is how to go about addressing this problem that everyone recognizes is not doing anyone any good. But we recognize that there is a gridlock now. There is a paralysis, and we have to break this paralysis. And I am grateful that the Agriculture Committee is trying to break this logjam. I do hope that we can work together so that we can find agreement on the way to proceed.

Mr. MORRISON. I respect totally everything you have said, except you said that it is not doing anyone any good. I am just wondering if when we figure out this process which I hear you arguing for and it makes some decisions that some of the levels of carcinogenicity that we have been concerned about we don't need to be concerned about. That they, in fact, are negligible risks. I just want to make sure that you are not starting where we are now and saying we have to reduce everything if, in fact, the process that you approve of comes to the conclusion that in maybe some areas we have al-

ready gone farther than we need to to truly protect the public's health.

Ms. HINKLE. I would hope that we wouldn't stop simply because something has arrived at 10 to the minus 6. I think we need to continue to look at the various control measures that we are using against these pests and try to choose the lesser of the evils, of the lower and the safer alternative, then gradually as you proceed with this choice and this course over the years, then you will encourage some of the safer alternatives and you have actually reduced the load so that it truly is acceptable.

Mr. MORRISON. OK. Well, what I hear you saying is that you are very much for a process.

Ms. HINKLE. Yes.

Mr. MORRISON. And let us agree on that process and make sure that it is accurate and then apply it across the board. My perception has always been that through the years we need to know about that groundwater, we need to know about those other factors that are part of that individual's diet, but that individual is going to have to make some decisions on their own because some of the things I think Americans like, such as charcoal-broiled steaks that probably some people enjoyed over Labor Day, are going to come up on the negligible risk list as ranking pretty high.

But I hear you saying that the process is the important part of what we are doing right now, and I concur and I compliment your organization for that.

Ms. HINKLE. Information is valuable, too, such as charcoaling is not—it may promote carcinogens, and, equally, information about those foods that are anticarcinogenic such as broccoli and cabbage. I think information is very helpful to the consumer.

Mr. MORRISON. Everything as far as I am concerned should have a rating, and then each consumer can make up their own choice as to what in fact they are going to consume. I think that is what we are talking about.

Mr. ROBERTS. Would the gentleman yield?

Mr. MORRISON. I would yield.

Mr. ROBERTS. You could have said a barbecued apple instead of barbecued beef.

Mr. MORRISON. Well, however it comes out we will take our risks.

Mr. ROBERTS. If the gentleman would continue to yield, I want to make one point to Ms. Hinkle.

On the first page, third paragraph, with respect to pesticides registered before 1978, the data shall be submitted no later than December 31, 1994. I know you are concerned about the 12 years.

Ms. HINKLE. Yes.

Mr. ROBERTS. That is 6 years. And thereafter pesticides are registered on a 12-year cycle. I understand your concern about that, but I did want to point out that there is a shorter time frame as we go through the reregistration.

Ms. HINKLE. Good. Thank you.

Mr. ROBERTS. Thank you, Mr. Chairman.

Mr. BROWN. Thank you very much, Ms. Hinkle. Your testimony is invaluable, and I think we are going to convert some of the members of the subcommittee if we keep working on it.

Our last witness this morning is Ms. Janet Hathaway, staff attorney for the NRDC, and we welcome her here this morning.

Ms. Hathaway, without objection, your full testimony will appear in the record, and if you should wish to summarize it, you would be welcome to do so.

STATEMENT OF JANET S. HATHAWAY, SENIOR PROJECT ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Ms. HATHAWAY. Yes. Thank you, Mr. Chairman. I would like to summarize my testimony.

Mr. Chairman and members of the committee, thank you for this opportunity to testify before the subcommittee on H.R. 4937, the Pesticide Food Safety Act. I am Janet Hathaway, senior project attorney with the Natural Resources Defense Council, also called NRDC. NRDC is a nonprofit public interest organization dedicated to protecting public health and the environment through scientific research and legal advocacy.

First, NRDC would like to commend you for inclusion in this bill of expanded funding for integrated pest management, or IPM, programs to reduce pesticide residues. IPM promises to provide effective means of dramatically reducing pesticide residues without adversely affecting agricultural productivity. It deserves vastly improved private and Federal support.

However, it will be important to identify more precisely than the bill currently does the kinds of research programs which Congress deems particularly worthy of funding. The 6-year, \$150 million project included in the bill is vitally needed, but there are surely many hundreds of millions of dollars' worth of important IPM research. The \$25 million-per-year authorization level set by H.R. 4937 will only begin this important work.

In general, however, after closely examining H.R. 4937 NRDC has concluded that we cannot endorse the bill. H.R. 4937 grants the Environmental Protection Agency and the Food and Drug Administration broad discretion which could be used to better protect our food supply from carcinogenic and otherwise hazardous pesticides. However, neither FDA nor EPA have wisely used the broad discretionary authority they currently enjoy to adequately protect the public. Often ambiguities in the statutory language have been exploited to condone current practices even when those practices pose a clear hazard to public health.

The histories of both EPA and FDA provide ample evidence food safety is often compromised even when statutory mandates are clear and unequivocal. Both agencies' neglect of the explicit prohibitions in the Delaney Clause demonstrates an unwillingness to tighten or eliminate certain uses of pesticides even when they are both hazardous and clearly illegal.

H.R. 4937 won't ensure enhanced protection of our food supply. First, the reregistration provisions do not include deadlines that are needed to ensure that all pesticides are re-evaluated in the next 9 years. NRDC strongly supports accelerated reregistration of pesticides which were licensed for use without complete data on health and environmental effects. In the 99th Congress NRDC was one of the principal groups involved in negotiations with the Na-

tional Agricultural Chemical Association, or NACA, which led to a detailed reregistration schedule now incorporated in the FIFRA reauthorization bills, H.R. 2463 on the House side and in the Senate S. 1516.

We continue to strongly support the reregistration provisions of H.R. 2463 which were recently adopted by this subcommittee and which are expected to be brought before the full committee soon. However, we don't endorse the reregistration section of this bill. We believe that the provision is insufficient to ensure rapid and orderly reregistration of all pesticides which still lack complete data.

Second, H.R. 4937 would not establish a strictly health-based standard for regulating pesticides in all foods. H.R. 4937 would require EPA to use one single standard for regulating pesticides in both raw and processed foods.

Unfortunately, NRDC does not believe the new standard will improve public health protection from carcinogenic and otherwise dangerous pesticide residues. One major reason why this is so is that the bill creates a negligible risk standard for oncogenic pesticides. NRDC considers this standard objectionable for three reasons.

First, the negligible risk standard is qualified by requiring EPA to give appropriate consideration to the risks and benefits of setting the tolerance. NRDC believes that this risk-benefit standard will be interpreted by EPA as a grant of authority to set pesticide residues at levels which pose hazards. To enable EPA to set tolerances at dangerous levels whenever it cites some benefit of the pesticide is a perversion of the purpose of the food and drug law. Benefits to the pesticide industry or to the food industry cannot cancel out real dangers for consumers.

Second, the bill's negligible risk standard for carcinogenic pesticide residues will not constrain EPA from asserting that high cancer risks are "negligible." Instead of requiring more protective standard-setting, this provision could insulate EPA tolerances which result in high risk to some portions of the population. NRDC believes that EPA should never be allowed to consider as negligible any risk of cancer or other serious disease which exceeds a rate of one in a population of 1 million.

Third, the bill does not identify what level of exposure to non-oncogenes is to be deemed safe.

Finally, NRDC believes many other provisions must be incorporated in H.R. 4937 to achieve a safe food supply.

First, tolerances should be set at safe levels for the entire population, including children and the elderly who may be more sensitive or more exposed to pesticide residues in food.

Second, EPA should be required to calculate exposures to pesticides at the legal limit; that is, the tolerance level.

Third, EPA's exposure assessments should calculate exposures to pesticides in all commodities and in drinking water.

Fourth, enforcement deadlines for EPA's obligations under this statute should be set by Congress.

Fifth, H.R. 4937 should require EPA to set tolerances for inert ingredients or metabolites of pesticides.

Sixth, H.R. 4937 should grant EPA needed imminent hazard authority so that it can modify and revoke tolerances expeditiously.

Seventh, H.R. 4937 should require practical methods for detecting pesticide residues before a tolerance is granted.

Thank you very much for the opportunity to testify on this bill. I do look forward to working with this committee on this legislation and on other bills which will be needed to enhance public health protection from pesticides in our food and in our environment.

[The prepared statement of Ms. Hathaway appears at the conclusion of the hearing.]

Mr. BROWN. Thank you, Ms. Hathaway.

Mr. Roberts.

Mr. ROBERTS. Yes. Thank you, Mr. Chairman.

I think I made reference in an earlier statement that we needed strong cooperation between all groups to get any kind of legislation passed; i.e., the FIFRA bill we passed during the last session of Congress three times, once by unanimous consent. We can't even decide when to adjourn around this place let alone, you know, pass a FIFRA bill. Three times we made progress. Of course, that died in the Senate and we are back to square one. Or, hopefully, not square one.

But, on the other hand, being a former newspaperman, this business of an adversarial relationship, I don't want to perjure that entirely. And I can remember when writing maybe golden words of truth in the editorial that I think would be very appropriate, why people would accuse me of being an adversary. And I said, "I was just trying to shine the light of truth in the darkness." Then they would say, "Yes, but you held the flashlight and it was a very selective process."

But I credit your organization in terms of prodding agriculture, if you will. I said earlier that we must step up to this challenge and be much more, I think, aggressive. My colleague from Washington pointed out that when the NAS made their study there was a lot of hesitancy on the part of the agriculture community; i.e., there was a lot of press about I think it was killer tomatoes or something at that particular time. We thought, "My gosh. We don't need another report that is going to come out and denigrate our food supply and all of this." But we have to do this. Mr. Waxman has a bill. We have a bill. And we look forward to working with you.

Let me ask you a question. Why do you think the EPA and the FDA have chosen to try and side-step the Delaney Clause? Why is Delaney, apparently, so problematic for these agencies?

Ms. HATHAWAY. Well, I think that there has been a tendency to focus on new pesticides or new products that would fall under the Delaney Clause rather than the old ones, primarily because old products that already have a market share have very vociferous advocates that EPA and FDA don't really want to tangle with. It is much easier to simply deny a registration of a product for either a food additive use or a pesticidal use than it is for either FDA or EPA to eliminate a use that has already been sanctioned in a sense by the grant of a tolerance.

Another reason why they are very leery of tampering with these old uses is that in 1977 Congress really slapped FDA hard when FDA banned saccharin. Congress overturned the ban on saccharin even though saccharin was—and still is—definitely carcinogenic. But many consumers were using the product and had developed a

kind of allegiance to that product, and therefore Congress responded by overturning FDA's fairly courageous action. Therefore, I think you will not see too much of that kind of action with old pesticides or old food additives unless the law is changed.

Mr. ROBERTS. Well that is precisely—I know your organization has stated that we don't have adequate data for food-use pesticides to accurately assess their long-term effects—I am now quoting—that is why I want an aggressive reregistration program. And you heard the NACA representatives being very nervous about that, understandably so, and yet we are getting a lot of suggestions—I would say criticism, but I will say suggestions—that we really won't accomplish anything by the risk reduction. If we go through the reregistration process, obviously these products are not going to be protected to the extent that you worry about. And I think that would be progress.

By the way, I have saccharin and sugar up here, and in defense of my sugar producers I use the sugar. I guess I am more safe when I do that.

Mr. MORRISON. A little fatter.

Mr. ROBERTS. A little fatter, as my colleague from Washington has pointed out.

I think at this juncture in the interest of time, Mr. Chairman, I will yield back. But I do want to thank the witness and I look forward to working with her.

Ms. HATHAWAY. Thank you.

Mr. BROWN. Mr. Stenholm.

Mr. STENHOLM. Ms. Hathaway, does your organization require a zero tolerance in the incineration of or disposal of a hazardous chemical?

Ms. HATHAWAY. Well, if we are talking about the food supply and determining that some chemical is posing greater than a negligible risk in the food supply, NRDC is on record that we could live with a bill that allows a very short interim time period in which we are phasing down the risk to the negligible level. We will not condone, however, a bill that does not constrain very narrowly what is meant by negligible risk. We would never approve of a bill, for example, that allows EPA discretion to set a negligible risk level higher than 10 to the minus 6, or one cancer out of a million people exposed over a lifetime.

When it comes to a hazard that is extreme, there are many instances in which a risk reduction can be undertaken that doesn't necessarily mean elimination of the chemical use altogether. For example, I have talked to a number of growers of apples in the Northeast who are convinced that some pesticide products that are clearly carcinogenic, many of the fungicides, could be used at extremely reduced concentrations than the ordinary farming practices entail if integrated pest management and scouting for insects were routinely incorporated into the farming practices. That is the kind of thing that we envision a bill like Mr. Waxman's bill doing, requiring that there actually be reduction in the residue level, not necessarily meaning that the chemical has to be eliminated entirely from the market.

But assuming that there are cases in which the chemical can't be used safely, because if it is used at such low levels it is simply not

effective, then we do support the concept that the registrant should conduct a recall of the product through the regular chains of distribution. When the product is returned to the registrant, the registrant should have to supply a plan to EPA under the RCRA authorities—the Resource Conservation Recovery Act authorities—to detail how exactly they are going to dispose of it. The disposal plan should not pose a significant risk to public health or the environment. That is the standard. That doesn't mean no risk at all.

Unfortunately, there are going to be risks associated with disposing of these products as well as using these products. But we would want those risks to be reduced as far as they can be.

What I am saying is we don't believe there is any place where we are going to have perfection. We aren't a group that has ever seen it as possible to take a hazardous chemical out of the food supply and dispose of it with zero risk to all people. There are workers who are going to be involved in collecting the product. There are people who are going to have to develop a plan for disposal. All those people who have some exposure to the product bear some risk. It is not avoidable as far as we can see.

Mr. STENHOLM. I think I am going to quit while I am ahead.

Mr. BROWN. Mr. Morrison.

Mr. MORRISON. Ms. Hathaway, your statement is rather critical of the efforts of my colleagues to get us moving in a positive direction, and maybe you have answered this in your response to the gentleman from Texas on disposal. But does any relative risk standard potentially meet the requirements of NRDC?

Ms. HATHAWAY. Yes. It is possible for a bill to be constructed that will in our view in fact reduce risks below the 10 to the minus 6 level for all carcinogens and would not allow EPA to play a shell game and to hide risks. What we fear most is that a bill that is very well intentioned, such as this effort, could be used by EPA to understate risks.

For example, one of the things that we want to have very well laid out in a bill of this kind is how is EPA to estimate exposure. EPA has had a practice of looking at average exposure, and virtually nobody really eats the average amount of apples. What EPA has looked at is the entire population as potential consumers of apples, and it has divided the total amount of apples consumed by the total population. If you are an apple eater and you occasionally eat an apple, you are definitely going to be substantially above that theoretical average that EPA has calculated. And we have looked at the EPA's tolerance-assessment system data and found that people who eat a high amount but not an extreme amount like in the 90th percentile of apples, eat 140 times what the average person does.

So we want to make sure EPA looks at the actual exposures people have and does not just look at some theoretical average that is really unrealistically low for what people are truly consuming of these commodities. That is one example of how we would limit agency discretion and come up with a bill that really is workable. That would not hide the real risks that pesticides pose.

Mr. MORRISON. I think all of us here would agree that whatever we come up with has to reflect the real world, and I trust that is the process you are describing. I am glad you used apples as the

example because as an apple grower myself our policy has been always to eat whatever you can't sell. And so I want you to know that after 55 years of doing that I am extremely healthy, and proud of the fact, even though I have consumed more than my share of carcinogens.

Thank you very much.

Mr. BROWN. Do you have any further questions?

Mr. ROBERTS. No, sir.

Mr. BROWN. Thank you very much, Ms. Hathaway.

Ms. HATHAWAY. Thank you.

Mr. BROWN. I think that in deference to the fact it is now noon we will excuse you. And we appreciate your testimony very much.

And the subcommittee will be adjourned.

[Whereupon, at 12 noon the subcommittee was adjourned, to reconvene subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

PESTICIDE FOOD SAFETY ACT OF 1988

Invited Testimony
by
Charles M. Benbrook, Ph.D.*

Mr. Chairman, Congressman Roberts, and other members of the subcommittee, it is indeed a privilege and great honor to appear before you today to address the "Pesticide Food Safety Act of 1988."

This bill, and this hearing will hopefully mark an important step forward in the pesticide oversight and legislative activities of the DORFA subcommittee. During the subcommittee's extensive oversight of EPA regulatory actions and policy changes in 1982-1983, your efforts brought to light the Agency's ambivalence regarding how to treat residues of potentially cancer-causing pesticides in food. In 1983 Chairman Brown wrote the Agency, raising a variety of questions about EPA's interpretation of the Delaney Clause, its applicability to pesticide residues in food, and its plans for dealing with the dual standards for regulation inherent in the Food, Drug, and Cosmetic Act (FDCA) and FIFRA statutes.

Chairman Brown's letter provoked EPA to assess its own policies in this area, and no doubt contributed to the Agency's decision to commission the National Research Council's Board on Agriculture to assist the Agency in developing a scientifically sound basis for the regulation of oncogenic residues. The findings, conclusions, and recommendations of the NAS study are contained in the report Regulating Pesticides in Food: The Delaney Paradox (National Academy Press, 1987). A copy of this report was provided to members of the subcommittee and staff upon its release in May 1987.

Discussions since the report's release, and a variety of other events (i.e. Court of Appeals decision on de minimus, Proposition 65) have served to sharpen public understanding of the regulatory dilemma faced by EPA in carrying out its statutory responsibilities. And now with the introduction of the "Pesticide Food Safety Act of 1988," the subcommittee has progressed from oversight and problem definition to the drafting of legislative remedies. The subcommittee deserves great praise for the courage and commitment needed to exercise both its oversight and legislative responsibilities in this highly controversial and extremely complex area of regulatory and public health policy.

*Testimony presented September 7, 1988 before the Subcommittee on Department Operations, Research, and Foreign Agriculture (DORFA), Committee on Agriculture, U.S. House of Representatives. Dr. Benbrook is the Executive Director of the Board on Agriculture, National Research Council, National Academy of Sciences.

Principal Recommendations of the NAS Report

Regulating Pesticide Residues in Food: The Delaney Paradox (hereafter referred to as the Delaney Report) made four principal recommendations. Herein I describe the relationship between provisions in the "Pesticide Food Safety Act of 1988" (hereafter referred to as the Roberts-Brown bill) and the NAS Delaney report.

First, two important points deserve note. The NAS committee which carried out the study and produced the report was not asked, and did not dwell at length on the need for, or substance of legislation to implement its recommendations. The committee felt that its recommendations could, in large part, be acted upon administratively, or through legislation, or through a combination of legislative and administrative reforms.

Since completion of the project, the adverse Court of Appeals decision regarding the legal basis of the Food and Drug Administration's de minimus policy has weakened the likelihood that EPA could implement the report's recommendations administratively and withstand legal challenge, which would likely follow. Legal experts differ both in their views regarding the ultimate scope of the recent Court of Appeals decision, and whether and how litigation might evolve if EPA moves ahead to administratively adopt a negligible risk standard.

A second key point--the NAS committee viewed its four principal recommendations as interrelated and interdependent. It felt that a strong case could be made for each of its recommendations, both on scientific and policy grounds, but only when adopted as a package. The reason for this important caveat will soon become evident.

Recommendation 1: Consistency

"Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current law and regulations governing residues in raw and processed food are inconsistent with this goal." (Delaney report, page 11)

To a large extent, this consistency recommendation both drives and shapes the other recommendations. It also poses the principal statutory challenge this subcommittee must resolve in crafting legislation.

The Roberts-Brown bill addresses head-on the major statutory provisions that give rise to inconsistent treatment of oncogenic pesticide residues in food:

- * The inconsistency between how residues in raw commodities and fresh produce are treated, in contrast to processed foods is eliminated in a straightforward fashion in Title II. Pesticide residues that concentrate on processed foods are removed from

Section 409 of the FDCA, and hence outside the reach of the Delaney Clause.

- * The inconsistency between new and old pesticides is addressed in Title I, which proposes a simple, yet far-reaching change in the re-registration provisions of FIFRA. By making re-registration the functional equivalent of registration, the Roberts-Brown bill would provide EPA a much more realistic statutory mandate and process with which the Agency could assess and regulate new and old pesticides with a consistent set of rules and scientific criteria.

While an elegant analytical case can be made for consistent treatment of pesticide residues, plain old common sense provides perhaps the most compelling basis for striving toward consistency. But how can EPA work toward consistency, short of either canceling all food uses of oncogenic pesticides, or leaving all such uses essentially unregulated?

Recommendation 2: Adoption of a Negligible Risk Standard

"A negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits." (Delaney report, page 12)

The need for and nature of this recommendation is best described in the committee's own words:

"The committee believes that the elimination of oncogenic pesticide residues from human food is an appropriate aspiration of regulation. The committee recognizes, however, that residues of several dozen oncogenic pesticides may be found in hundreds of different foods. Many such residues pose little risk to humans, whereas some clearly warrant attention and, quite probably, regulatory action. The problem of implementing action against many pesticides with limited personnel and resources should be minimized. Moreover, the challenge for regulators grows increasingly complex as science and technology advance. Improvements in analytical chemistry and residue detection capabilities, new toxicological data, changing pesticide use practices, and the development of new pesticides and foods establish an urgency and the feasibility to devise a strategy for attaining a safer food supply." (Delaney report, page 12)

The Roberts-Brown bill calls for the application of such a standard in establishing, reviewing, adjusting, and when necessary revoking tolerances for oncogenic pesticide residues in fresh and/or processed foods.

Moreover, the language in Section 204 of the Roberts-Brown bill provides the Administrator clear and appropriate guidance regarding how to apply the standard. As recommended in the Delaney Report, the bill would:

- * Apply a negligible risk standard to the estimated dietary risk from exposure to a given pesticide used on a given crop, taking into account residues in or on both fresh and processed foods derived from the crop.
- * Require EPA to use realistic assumptions and the best available data in developing risk estimates, and when comparing risks associated with one pesticide in contrast to risks from other pesticides registered for the same crop use or uses.

Another key point deserves mention. The NAS committee discussed at virtually every meeting whether to recommend a quantitative benchmark for negligible risk as part of its definition of this important concept. The committee was both sensitive to and well aware of valid arguments both for and against specifying a quantitative benchmark in the definition of negligible risk. In the end, the committee was persuaded that quantitative risk assessment methods, and the science underlying estimates of oncogenic risks, were too fragile and changeable to either assert that risks below a certain level are truly "negligible," or that risks above the "negligible" level indeed pose a significant risk of cancer in man. Such judgments, in the committee's view, can only be made on a case-by-case basis following a thorough review of the complete toxicological database available on a particular chemical. Even then, such judgments may be very hard to make.

In the absence of a defensible scientific basis to establish a quantitative benchmark for negligible risk, the committee felt constrained to merely define what it meant by such a risk level, while utilizing 10^{-6} as one commonly accepted benchmark in its analytical exercises. For many years regulatory officials in EPA, FDA, and other agencies will continue to face a difficult set of scientific and policy issues in reaching judgments regarding negligible risk. The language and approach taken in the Roberts-Brown bill regarding the definition of negligible risk is sensitive to, and consistent with the NAS committee's findings and recommendations regarding the need for consistent application of a negligible risk standard.

Recommendation 3: Target High-Risk Pesticides and Crop Uses

"The committee's analysis (described on pages 50-66) suggests that about 80 percent of oncogenic risk from the 28 pesticides that constitute the committee's risk estimates is associated with the residues of 10 compounds in 15 foods. Logic argues that the EPA should focus its energies on reducing risk from the most worrisome pesticides on the most-consumed crops, and compelling reasons support such a strategy."
(Delaney report, page 14)

A great deal of additional research on the magnitude and distribution of oncogenic pesticide residues (and risk) in food have been undertaken, and is ongoing within EPA, state regulatory agencies, private organizations, and academic institutions since the May 1987 release of the NAS Delaney report. While individuals differ markedly in their view of the magnitude and true significance of pesticide-related cancer risk, there is now widespread agreement that both exposure and potential risk is heavily concentrated in relatively few foods following the use of perhaps a dozen oncogenic pesticides.

In contemplating the challenge EPA faces in re-registering some 200 plus food use pesticides, this point takes on great significance. If and as EPA determines that some pesticide risks indeed exceed a negligible level, and further finds that risks exceed benefits, the Agency can substantially reduce risks by targeting regulatory action toward the relatively few pesticide uses associated with the greatest risks. For the farm community, the other side of the coin is reassuring--most current uses of potentially oncogenic pesticides contribute very modestly, if at all to dietary cancer risk, and hence are not likely to warrant severe regulatory restrictions, at least not on the basis of dietary cancer risks.

The three preceding recommendations constitute both an approach, and a new set of rules for establishing tolerances and regulating oncogenic pesticides. The last recommendation addresses the need for EPA to augment its current approach to risk assessment and risk-benefit balancing through adoption of an analytical framework designed to facilitate two key goals--highlighting the relative risks and benefits associated with the use of all the pesticides registered for control of a given pest on a given crop; and second, assisting the Agency in assuring that its regulatory actions actually reduce total risk after crop producers have switched to other products following a regulatory action.

Recommendation 4: Adoption of an Analytical Framework

"The EPA should develop improved tools and methods to more systematically estimate the overall impact of prospective regulatory actions on health, the environment, and food production. Rapid advances in computer technology, as well as the EPA's successful efforts to computerize major data sets like the Tolerance Assessment System (TAS) make such progress readily attainable." (Delaney report, page 15)

The committee explained the need for such a framework by pointing out that:

"Use of new analytical tools and data bases could help the EPA get ahead of its growing work load. The refinement of such a system would allow the EPA to project with increased confidence a wide range of impacts associated with its regulatory actions. For example, the committee's rudimentary analysis demonstrates that certain strategies for implementing

the Delaney Clause could increase dietary risk, and vigorous application of the Delaney Clause to tolerances for residues in processed foods may not be the most effective strategy for minimizing dietary exposure to oncogenic pesticides." (Delaney report, pages 15-16)

As stated earlier, the committee felt that its four recommendations were justified when considered as a package. It would remain extremely difficult for EPA to target high-risk uses of pesticides without a new analytical framework, nor strive toward consistency in applying a negligible risk standard to new and old pesticides, and residues in fresh and processed foods.

The committee felt compelled to point out one particularly key linkage among its recommendations:

"The adoption of a negligible-risk standard would provide added justification for the agency to reduce relatively high risks while deferring actions on relatively low or perhaps even zero risks. The committee would not endorse the adoption of such a standard if it were not consistently applied to all pesticides and all forms of human food." (Delaney report, page 13)

Legislative Proposals Impacting Re-registration

For the last several years the subcommittee has passed legislation containing an extensive set of amendments involving the re-registration process. Indeed, many people consider the amendments developed to accelerate the re-registration process as the most important feature of the legislation the full Committee on Agriculture is scheduled to markup in the near future.

The relationship between the Roberts-Brown bill re-registration provisions and those in the FIFRA bill passed earlier this month by the subcommittee warrants some discussion. Put simply, the amendments address different issues, and are very different in content. They are not mutually exclusive. Prior to full committee markup, I would urge the subcommittee to consider how the two provisions could be integrated.

The key change proposed in the Roberts-Brown bill is simple: it would make re-registration the functional equivalent of registration. Many people erroneously assume that this is indeed now the case with the current FIFRA. While the language of FIFRA could arguably be read in support of the notion that registration and re-registration are the same, in practice the two actions are very different.

In the case of reviewing an application for a new registration, the Agency requires the applicant to meet all applicable data requirements before reaching a decision regarding potential risks, and moreover the

burden rests on the applicant to prove that risks are slight, and that benefits exceed risks. The product is not allowed on the market until proven safe.

In the re-registration process, the shoe is on the other foot. EPA is compelled to leave a pesticide product on the market despite datagaps, and even when there are rather clear indications of significant risk. For most active ingredients, the first several years of the re-registration process entails little more than identifying and filling datagaps. Once the data is in, EPA then proceeds to conduct a new risk assessment. If it determines that the risks from some uses are potentially excessive, the Agency then has to initiate either the special review or cancellation processes, which generally take a few more years, at a minimum, to complete. Only then are benefits seriously evaluated.

Under current law, the decision to not re-register a pesticide only triggers the beginning of another protracted, costly administrative process. This is why Dr. Moore of EPA repeatedly highlights the statute itself as a principal constraint in working through the backlog of chemicals that are winding their way through re-registration.

The Roberts-Brown bill goes to the heart of this problem by changing the standard EPA is required to apply when considering an application for re-registration, and by furthermore conferring regulatory significance to a decision not to re-register a pesticide. It also deals with the very real issue of Agency resources by placing the burden on registrants to apply for re-registration, and submit with such an application a complete dataset (which will no doubt include references to data already submitted to the Agency). Last, it would extend the routine re-registration period from 5 to 12 years, in recognition of the fact that a pesticide which can meet the current standards for safety and efficacy, based on a complete and up-to-date dataset, is likely to remain a valuable and safe product for many years to come. As a practical matter, a thorough review of all old pesticides once every 12 years would do far more to protect the public health than the type of piece-meal, step-wise assessment that occurs today.

The extensive re-registration amendments in the subcommittee passed bill would establish a five phase re-registration process taking an estimated 9 years to complete. Several provisions are both needed and clearly compatible with the Roberts-Brown bill. Specifically, it would be desirable to retain the fee structure and related amendments from the subcommittee passed bill in any future package of re-registration amendments; the penalty provisions in the subcommittee bill for non-compliance with the procedural requirements of the re-registration process also belong in any future set of amendments, as well as provisions addressing inadequate or fraudulent data.

The major differences in the two bills are the change in the standard, and the extension of the re-registration time period from 5 to 12 years. The timetable called for in the two bills is very similar, and could easily be reconciled.

One important point deserves emphasis relative to timetables. The NAS Delaney report, and other reports and studies have documented that the risks associated with current pesticide use patterns are highly variable. Relatively few pesticides account for the lions share of risk; just a few uses for the riskiest pesticides account for the bulk of exposure; water quality and other environmental problems generally arise from certain combinations of soil type, climate, and application methods; worker safety problems reflect particular combinations of practices, in the absence of recommended safety precautions, and so.

As a result, the public health and environmental goals of FIFRA would be advanced most cost-effectively by providing EPA authority and flexibility to target its re-registration, special review, and cancellation efforts at those pesticides which appear most worrisome. EPA has a pretty clear idea of which products belong in this category. It would be preferred for EPA to select 15 of the most hazardous products, and act to reduce risks to acceptable levels from them over the next 24 months, rather than to work its way through the first two or three of five phases of re-registration on some 600 active ingredients. In striving to provide a statutory mandate to implement the NAS report's recommendations, the Roberts-Brown bill would go a long way toward focusing Agency resources and effort on potentially significant risks.

In summary, I believe it is fair to say that the provisions of the Roberts-Brown bill would substantially reconcile within the FDCA and FIFRA statutes the principal statutory constraints EPA faces in implementing the four major recommendations in the NAS Delaney report. Please note my choice of words--it was deliberate.

The Roberts-Brown bill would provide EPA critical new authority, tools, and direction. It would not, nor can any legislation, dictate that such new authority be exercised with a sense of urgency and commitment to reducing public health risks. Moreover, as this subcommittee is well aware, there are many other factors which must realistically be taken into account, including--

- * Funding levels to support the re-registration process.
- * New developments in the scientific arena, including a rapidly growing database on pesticide risks stemming from surface-water and ground-water contamination.
- * State regulatory efforts and initiatives, like Proposition 65; ongoing litigation, and the prospect of new cases involving regulatory actions based upon a de minimus theory.
- * Political changes in the executive and legislative branches of government.

For better or worse, the DORFA subcommittee opened this can of worms. The issues were bound to arise, and pose tough choices both for Congress and regulatory officials. By crafting this bill and holding this hearing, the subcommittee has taken a commendable step forward in resolving a complicated, at times seemingly impenetrable regulatory problem. Thanks for the opportunity to appear before you this morning. I would be pleased to answer any questions.

(Attachment follows:)

**Atlas of
U.S. Cancer Mortality Among Whites:
1950-1980**

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service,
National Institutes of Health
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Results

U.S. Rates

Mortality rates between 1950 and 1980 rose most dramatically for lung cancer, with female rates rising 36% each five years compared to 20% for males (figure 2). Other striking increases (over 10% per five years) were seen in both sexes for malignant melanoma, multiple myeloma, and connective tissue tumors, and for laryngeal cancer among women. Rates for cancers of the lip and stomach in both sexes, and for non-melanoma skin and liver cancers among women, dropped over the same period by 19% or more per five years. Decreases of more than 10% per five years were also seen for cancers of the bone and rectum in both sexes, for cancers of the cervix, corpus uteri, nasal cavity, and thyroid gland among women, and for non-melanoma skin cancer and Hodgkin's disease among men. During the 1970s, the highest mortality rates were seen for lung, colon, and prostate cancers among men and for breast, lung, and colon cancers among women (figure 3). These sites, along with the corpus uteri, also had the highest incidence rates during this period.^{13,40}

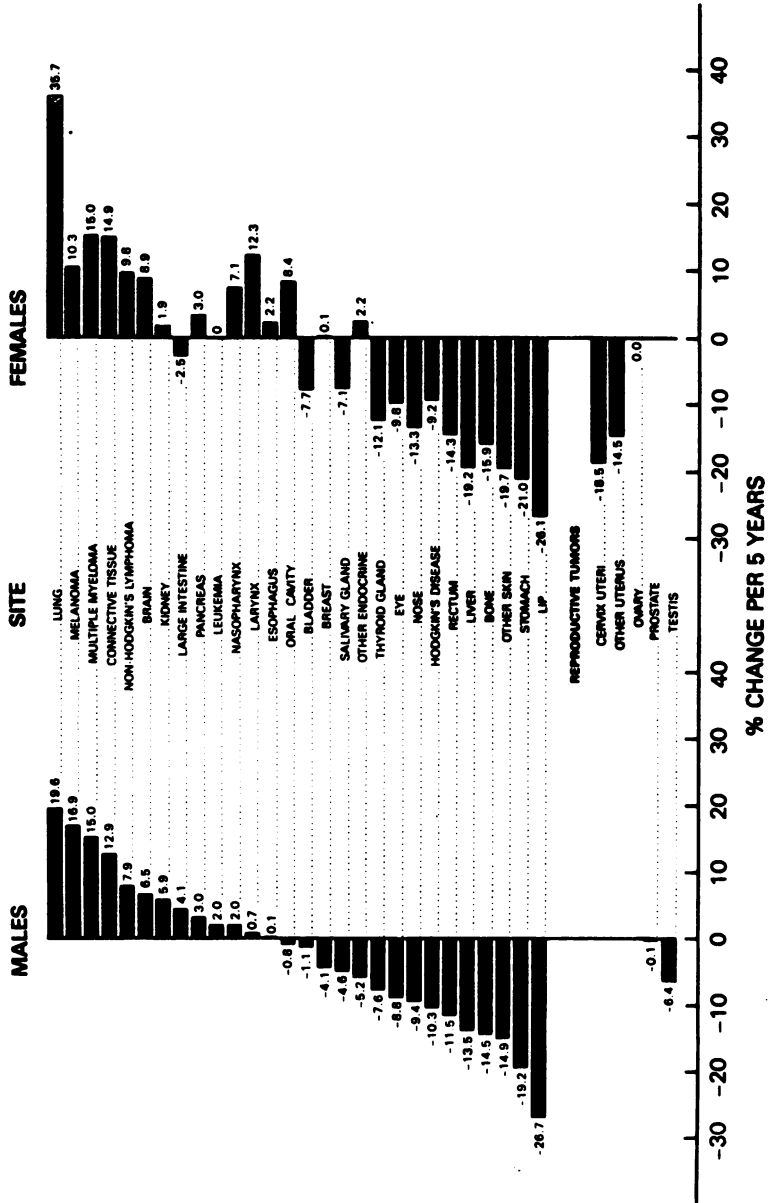
Although the model used to examine time trends fits the U.S. data very well, examination of those sites with a poorer fit pointed to noteworthy changes in the patterns of the rates over time. Sharp downturns in mortality rates for Hodgkin's disease and testicular cancer and a sharp increase for female lung cancer were seen during the 1970s for all age groups.

An examination of the interaction of age and time effects on the U.S. mortality rates identified certain cancer sites where patterns differed by broad age group (20-44, 45-69, 70+). The most common pattern revealed declining rates over time for the youngest age group but not for the others; this was the case for cancers of the colon, rectum, bladder, lymphomas, multiple myeloma, and leukemia for both males and females; breast cancer for males; and corpus uteri, thyroid, and other endocrine tumors for females. For malignant melanoma and connective tissue cancer, the rates for the youngest group increased slightly, compared to a greater increase over time for the older ages among males and females. For females, cancers of the oral cavity, esophagus, and larynx showed a decreasing trend for the youngest ages, an increasing trend for the middle ages, and a stable pattern for the oldest group. For brain cancer, rates for the oldest group of males and females increased dramatically over time, to surpass those of the middle age group which previously had the highest reported rates.

The mortality rate variability, as measured by the interquartile range, was similar for men and women for most sites during the 1970s, except for cancers of the bladder, rectum, colon, and oral cavity which showed at least a 20% greater variation among men. The degree of variability was largest in the 1970s for cancers of the lung, rectum, colon, lip, oral cavity, nasopharynx, and eye among both men and women (figures 4 and 5), bladder among men, and cervix uteri and breast among women. Leukemia showed the least variation for both men and women during this time period. The interquartile ranges for cancers of the eye, other endocrine glands, nasopharynx, and lip appear unusually large among women for the 1950s because over 25% of the SEAs had no deaths due to these causes. While an apparent homogeneity of rates (e.g., leukemia, cancers of the pancreas or prostate) does not preclude the existence of geographic clusters of high rates, it does indicate that on the whole rates are not as variable for these cancers as for others. For nearly all sites, the variability of rates has decreased over time (figures 4 and 5). However, a dramatic increase in rate variation has occurred for female lung cancer, indicating the emergence of wide geographic differences since the 1950s.

The general trend toward increasing homogeneity of cancer rates over time is further supported by a comparison of the overall U.S. rates with the corresponding medians of the distribution of the SEA-specific rates. The overall U.S. rate for a tumor which occurs predominantly in densely populated areas is higher than the median rate of the SEA distribution because the total number of deaths in the U.S. rate will be heavily weighted by these populous areas. In the 1950s, U.S. rates for several sites were more than 20% higher than their corresponding median rates (cancers of the nasopharynx, larynx, rectum, and endocrine system in both sexes; eye cancer in women; cancers of the bladder, colon, esophagus, and oral cavity in men). However, in the 1970s only a single cancer site (rectal cancer among men) revealed such a large difference. This measure of "urban effect" dropped for male lung cancer from an 18% excess in the 1950s to a 1% deficit (i.e., the U.S. rate 1% lower than the median) in the 1970s, indicating that increases in male lung cancer rates have been taking place mainly in less populous areas. Similarly, U.S. cervical cancer rates were below the median rates for every decade, indicating that deaths due to this cancer have been occurring more in less populous areas for at least 30 years.

Figure 2. — U.S. Cancer Mortality Time Trends, 1950-1980, by Site for Males and Females



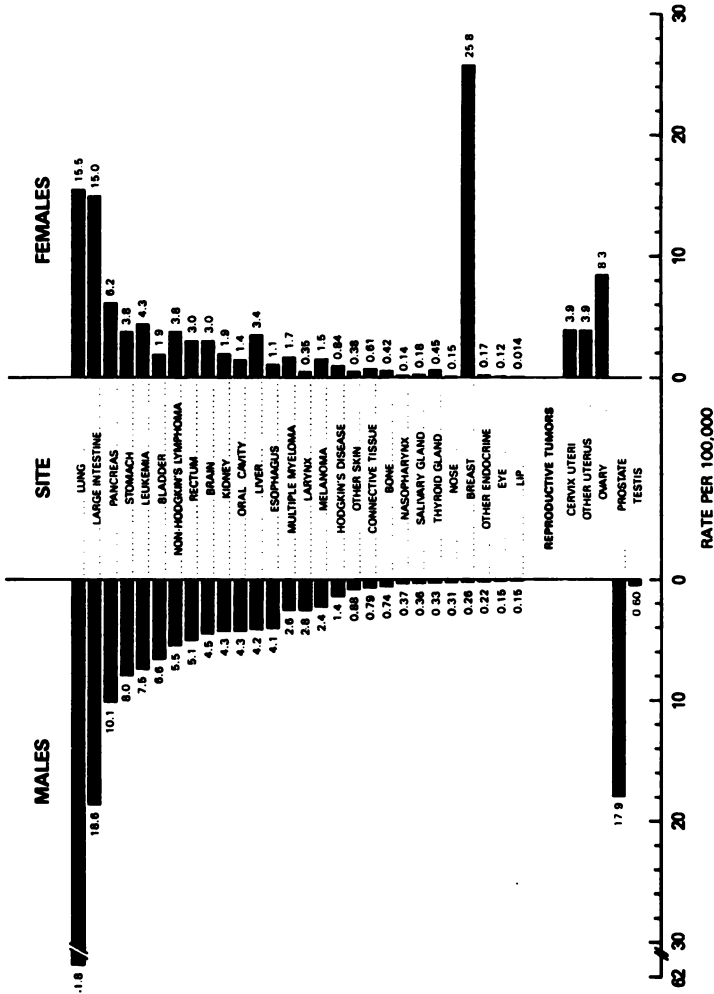
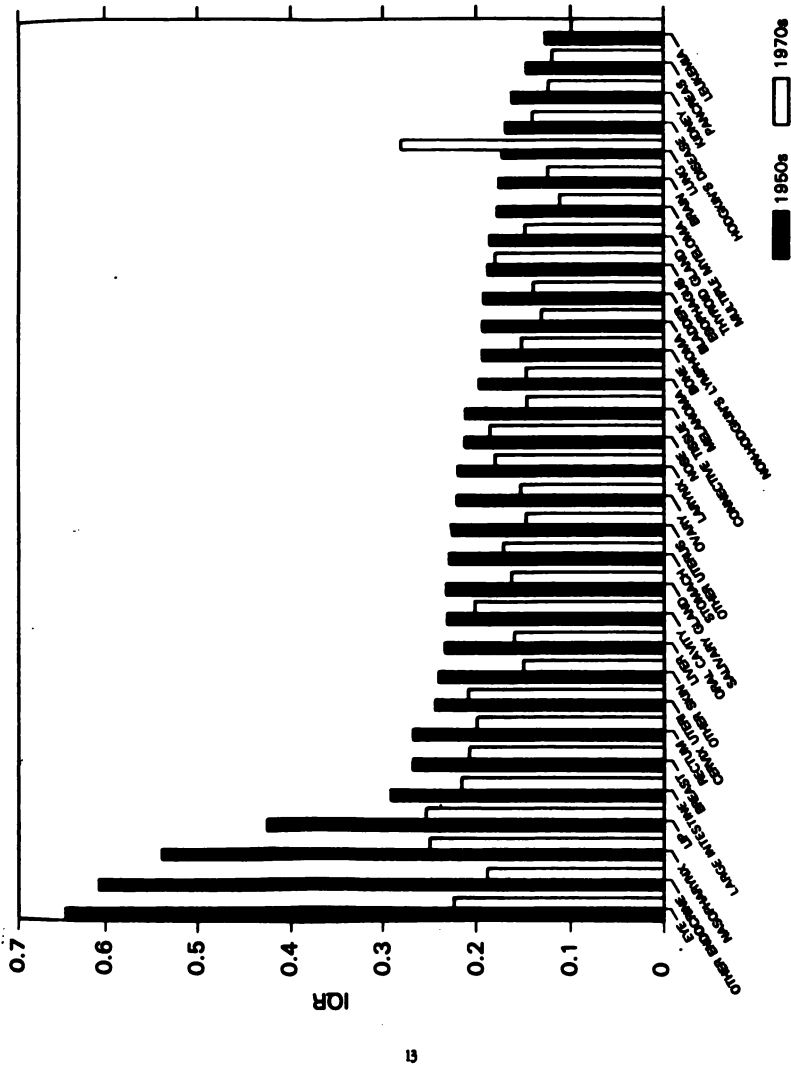


Figure 3. — U.S. Cancer Mortality Rates for the 1970s by Site for Males and Females



Geographic Patterns

Described below are the patterns for the most commonly occurring cancers, along with possible explanations based mainly on correlation and analytic studies conducted by the National Cancer Institute, usually in collaboration with other research groups, in response to earlier cancer atlases.

Oral cavity: Rates for men were high in all time periods in the urban Northeast, and in several metropolitan areas and port cities elsewhere. However, in the 1970s high-rate areas predominated along much of the east coast. The urban association among males appeared to correspond with levels of alcohol consumption and tobacco smoking, the major risk factors for oral cancer.⁴¹ Among females, however, the rates were highest in rural counties of the South, especially in the earlier time periods. A case-control interview study of North Carolina women implicated the long-standing habit of dipping snuff, i.e., placing finely ground smokeless tobacco between the gum and cheek.⁴² This cluster of oral cancer was less pronounced in the 1970s as rates among women declined in the rural South and high-rate areas appeared along the Pacific and Florida coasts. This newly-emerging pattern resembles that for female lung cancer, suggesting the influence of cigarette smoking.

Esophagus: Rates for men were elevated in urban centers, especially in the Northeast, although clustering in this area diminished in the 1970s. Among females, rates remained high in the urban Northeast and showed some increases in the Far West and Florida, while the high rates initially observed in scattered parts of the rural South became less conspicuous in the 1970s. The geographic patterns resemble those for oral cancer and suggest the effects of alcohol consumption, smoking, and possibly smokeless tobacco on both cancer sites.⁴³ Poor nutrition may also contribute to the patterns of occurrence, since dietary deficiencies seem responsible, along with alcohol intake, for the much higher rates of this cancer among blacks.^{44,45}

Stomach: The patterns for both males and females have featured a cluster of excessive mortality in primarily rural counties in the North Central region, which appeared correlated with the concentration of high-risk ethnic groups from northern Europe.⁴⁶ This cluster has become less apparent in the 1970s. A similar aggregation in certain southwestern states seemed related to the excess risk among the Hispanic groups in this area. Higher rates have also persisted in northern urban areas. In the face of substantial nationwide reductions in mortality over the 30-year period, rates in both sexes declined less rapidly in areas of New England, Appalachia (parts of OH, WV, VA, KY, TN), Florida, Texas and southern California.

Large intestine, excluding rectum: In both sexes there has been a consistent North-South gradient, with rates being higher in the northern parts of the country, partly due to the elevated risks of urban populations with higher socioeconomic levels.⁴⁷ Clustering has been most evident in the Northeast and Midwest. Also, the North-South differential has diminished with time, as more areas in the South have displayed rising mortality rates than in the North. Despite the lack of a sex differential in the geographic patterns, there has been a rising national trend in colon cancer mortality among males accompanied by a decline in females, most evident in the urban Northeast. It is interesting that the lower rates in the South have prevailed even in areas attracting large numbers of retirees from the North, thus prompting a case-control study in Florida retirement communities.⁴⁸ Preliminary data suggest there is no rapid reduction in risk of colorectal cancer, but the younger the age at migration, the lower the risk. It remains to be seen what aspect of the southern environment or lifestyle may be protective. Another study opportunity was provided by a cluster of high rates in a rural agricultural area of eastern Nebraska. In a case-control interview study, the elevated risk of colon cancer was primarily among persons of Czechoslovakian background, who predominate in the study area.⁴⁹

Rectum: The geographic patterns for rectal cancer resemble those for colon cancer, suggesting risk factors in common. However, the rates are generally higher in males than females and have declined over time in both sexes, at least partly due to improvements in survival.

Liver, gallbladder, and biliary passages: These diseases were not separable by ICD code prior to 1958, so they are presented in combination for the entire time period. Mortality rates for liver cancer may be markedly influenced by the potential misclassification of metastatic disease as primary neoplasms. However, among females the geographic pattern for this category is consistent with previously identified high-rate areas of biliary tract cancer in the North Central region, the Southwest, and Appalachia.^{50,51} Mexican Americans, who reside primarily in the Southwest, and residents of Appalachian communities⁵² have a high incidence of gallstones, the major risk factor for biliary tract cancer.

Pancreas: In all time periods the amount of geographic variation was less evident than for most other tumors. Nevertheless, clusters of high-rate areas were seen in the urban Northeast and in Louisiana and the Mississippi delta area. In general, the rates for pancreatic cancer have been greater in urban areas and highly correlated with the patterns of lung cancer, especially in males, suggesting the influence of smoking habits on both tumors.⁵³

In a case-control study in southern Louisiana, preliminary results suggest that smoking patterns and dietary habits may contribute in part to the high rates in this area.⁵⁴

Nose, nasal cavities, and sinuses: There is little evidence of geographic clustering of these rare tumors, but a correlation study suggested a possible link between employment in the furniture manufacturing industry and risk of nasal cancer.⁵⁵ A case-control study based on death certificates revealed an excess risk associated with woodworking occupations.⁵⁶ Subsequently, a case-control interview study in Virginia and North Carolina indicated increased risks of nasal adenocarcinoma among furniture workers and textile workers, while increases in squamous cell cancers were related to cigarette smoking.^{57,58}

Larynx: Among males, excess mortality has persisted in the Northeast corridor and in urban areas elsewhere in the country. While rates have declined in the urban Northeast, a cluster of high rates has emerged in New England. Rates have also tended to increase in the Midwest and North Central states, and more generally in rural areas throughout the country.⁵⁹ The distribution of laryngeal cancer has been correlated with lung, esophageal, and oral cancers in a manner consistent with the action of tobacco and/or alcohol consumption on the risk of these tumors. Elevated mortality from laryngeal cancer has been reported in coastal areas where shipyards operated during World War II,⁶⁰ consistent with some reports implicating an effect of asbestos exposure, but a case-control study of laryngeal cancer in coastal Virginia revealed no excess risk associated with shipbuilding.⁶¹ Among females, there has been a rapid increase in mortality throughout the country, with high rates emerging in the 1970s in the Northeast and in California.

Trachea, bronchus, lung, and pleura: Among males the mortality rates in the 1950s were high in urban areas of the North and in certain seaboard areas of the South, especially along the southeast Atlantic and Gulf coasts.⁶² The geographic pattern appeared consistent with variations in smoking habits and with occupational exposures, including shipbuilding and ship repair.⁶³ Case-control interview studies in coastal areas of Georgia,⁶⁴ Virginia,⁶⁴ and Florida⁶⁴ revealed an elevated risk of lung cancer associated with shipbuilding, especially during World War II. In coastal Virginia a cluster of mesothelioma was identified and also linked to shipyard exposures to asbestos.⁶⁵ Case-control studies are under way to clarify reasons for the high rates along the Gulf Coast, and preliminary analyses of Louisiana data suggest an excess risk among the Cajun population, due at least partly to smoking practices, including the heavy use of hand-rolled cigarettes.⁶⁶ During the 1970s the elevated mortality declined in the Northeast and became more pronounced in the South, both in rural and urban counties.⁶⁷ A high-rate cluster in

Louisiana extended inland along the Mississippi River. Among females the rate of increase rose sharply throughout the country in the 1970s, with aggregations of high rates in Florida and along the mid-Atlantic and west coasts.

Breast: The geographic patterns have remained relatively stable over time, with most low rates in the South and high rates concentrated in the Northeast, especially in urban areas. However, the North-South differences have diminished, in association with rising rates in many areas of the South, notably in Appalachia. When the geographic patterns were analyzed by age group, only postmenopausal women (55+ years) showed a northern predominance, along with ethnic correlations and positive socioeconomic gradients.⁶⁸ In contrast, the rates for premenopausal women (20-44 years) were distributed almost uniformly across the country and correlated most closely with county birth rate (fertility) characteristics.

Cervix uteri: High rates were scattered throughout the South, with the heaviest concentration in Appalachia, which correlates with the tendency of this tumor to affect rural women in the lower socioeconomic classes.⁶⁹ Rates in the North remained low except for parts of northern New England. Although mortality has declined substantially throughout the country, the rates in several midwestern states decreased less rapidly, so that in the 1970s a cluster of relatively high rates appeared in these states as well as in Appalachia.

Corpus and other uterus: Some clustering of relatively high mortality rates has persisted in the mid-Atlantic and midwestern states. Mortality has declined nationwide, but less rapidly in the North Central and Far Western states. Because of favorable survival rates and the potential misclassification of cervical cancer deaths, the mortality pattern for this cancer is much less informative than incidence data. The latter have revealed regional and temporal variations that correlate with the use of estrogens prescribed at menopause.⁷⁰

Ovary: Mortality patterns have shown little change, with scattered high rates in both urban and rural areas across the northern part of the country and in some urban areas along the West Coast. A correlation with the distribution of breast cancer has been described.^{68,69}

Prostate: Although geographic variation is rather limited, some clustering of high-rate areas persisted in the northeastern and North Central states, particularly in rural areas. Rates over time remained generally stable, except for some clustering of areas with rising rates in Florida and California. Correlation analyses have suggested that ethnic factors may influence the distribution of this cancer.⁷¹

Testis: There is little indication of geographic aggregation for this disease. Despite an upward trend in incidence rates, mortality from testicular cancer has dropped precipitously with improvements in therapy and resultant survival rates.^{72,73}

Kidney: In both sexes the rates for renal cancer have remained elevated in the North Central region, with some high-rate areas also in the Northeast. The North-South differential declined over time as rates in the South rose more rapidly than in the North, especially in males. In Minnesota a case-control study of renal adenocarcinoma (which comprises about 85% of renal cancer) revealed elevated risks associated with German and Scandinavian ancestry, which partially explain the geographic variation.⁷⁴

Bladder: Among males, bladder cancer rates were consistently high in urban and rural areas of the Northeast, in urban areas around the Great Lakes, and in southern Louisiana. Over time the high-rate areas became more pronounced in the midwestern states, including Ohio and Michigan, and time-trend analysis showed that rising rates were most evident throughout the central portion of the country. Among females, high-rate areas were seen mainly in upstate New York and New England. Occupational factors appeared to contribute to the geographic distribution among males, with rates particularly high in counties where the chemical industry is heavily concentrated.⁷⁵ A series of case-control studies in high-rate areas revealed excess risks among workers exposed to various chemicals,⁷⁶ and among truck drivers and others occupationally exposed to motor exhausts.^{77,78} In northern New England, preliminary analysis of a case-control study suggests that work in the leather and textile industries may contribute to the high rates for both sexes in that area.

Melanoma of the skin: A striking southern predominance has persisted over time, with both sexes showing high rates mainly in the Southeast and South Central regions. This pattern is consistent with the effects of sunlight exposure on the distribution of melanoma.⁷⁹ The mortality rates have risen in all parts of the country, although recently a high-rate area has emerged among males in California.

Other skin: Elevated mortality in the southern part of the country was seen also for nonmelanoma skin cancers, despite the low case-fatality rates for these common neoplasms. In incidence surveys across the country, the distribution of basal-cell and squamous-cell carcinomas of the skin was found to be strongly affected by the amount of exposure to sunlight.^{79,80} In contrast to melanoma, the death rates for other skin cancers have declined over time, especially in the South.

Brain and other parts of the nervous system: No clear pattern was seen except for scattered high rates for

both sexes in the Southeast. It is often difficult to distinguish between primary and metastatic neoplasms of the brain based on death certificate data, so that the geographic distribution may be influenced by variations in the quality of medical care and reporting systems.

Thyroid gland: In both sexes some high-rate areas were seen in the Rocky Mountain and North Central states. Overall there has been a steady decline in mortality rates.

Bone: High rates were seen in the Southeast among females, but geographic and temporal variations in mortality are confounded by fluctuations in diagnosis and reporting, especially the inclusion of metastatic tumors to bone.⁸¹

Connective tissue: Rates for both sexes have risen over time, with scattered high rates appearing in various parts of the country. In the 1970s a high-rate area emerged among women residing in West Virginia and Maryland. A rising incidence of this cancer has also been reported, but diagnostic and reporting practices probably contribute to the temporal and spatial variations of this tumor.⁸²

Hodgkin's disease: Mortality rates have declined over time for both sexes, associated with improvements in survival, but relatively high rates have persisted in the urban Northeast and in several North Central states. The North-South gradient in Hodgkin's disease applies mainly to young adults and has been invoked along with other risk factors to suggest a possible viral etiology.⁸³

Non-Hodgkin's lymphoma: In both sexes the rates were generally low in the South and elevated in the metropolitan centers and in coastal areas of California. This pattern seems related in part to socioeconomic status, which has shown a positive correlation with this neoplasm.⁸⁴ Over time there has been an upward trend in mortality rates, most notably in central and eastern areas of the U.S. Some clustering has appeared in North Central and midwestern states, especially in females. In a survey of death certificates from Wisconsin, an excess risk was detected among farmers.⁸⁵ In Kansas, where high rates emerged in the 1970s, a case-control interview study suggested a risk associated with the farm use of herbicides, especially phenoxyacetic acids.⁸⁶

Multiple myeloma: High rates were scattered throughout the North Central region, especially among males. An upward trend in mortality has been seen in all parts of the country, especially in people over 55 years of age, and elevated rates have been associated with urbanization and high socioeconomic level.⁸⁷ In a survey of death certificates in Wisconsin, an excess risk was associated with various agricultural occupations that deserve further study.⁸⁸

Leukemia: In both sexes, scattered high rates for adult leukemia were seen throughout the central part of

the country from Texas to Minnesota. The slight upward trend in mortality among males is also most pronounced in the central portion of the country. Many high-rate counties have been located in agricultural communities, notably cotton-producing areas where heavy pesticide use

is a common practice.⁴⁹ Case-control surveys of death certificates in Nebraska and Wisconsin have revealed associations with various agricultural activities, thus providing leads for further investigation.^{50,51}

Discussion

This publication has updated the earlier cancer atlas for the white population with 10 additional years of data and has evaluated the trends in cancer mortality by SEA over a 30-year period. Death registration has been required in all U.S. states for over 50 years. Although several earlier NCI monographs have examined the geographic distribution and time trends of cancer mortality,^{4,5,9} only recently have sufficient data become available to examine these patterns simultaneously in finer detail than at the state level. It is important to recognize that some geographic and temporal variations provide signals to environmental hazards, but for many tumors fluctuations in diagnosis, reporting, survival time, and migration may complicate the picture.

The mortality patterns for most cancers showed a tendency toward geographic uniformity over time, as reported previously using data by state or broadly-grouped counties.^{94,95} However, in our study the variation in rates was quantified in a way that allows for comparison of cancer sites. In particular, the decreasing rate variability for most cancers suggests a lessening of regional differences in the prevalence of risk factors. Increasing standardization of diagnostic measures and death certification practices may contribute to the reduction in geographic differences, as may the wider distribution of improved medical care and more favorable survival rates.

The maps presented here can be used to identify not only areas where cancer mortality rates are elevated, but also areas where rates are changing more rapidly than the average U.S. experience. The maps are reproduced in half-page size on facing pages to facilitate a comparison of geographic patterns over time. The 1970s map may be viewed as a supplement to the previous atlas, as the

statistical methods are unchanged except for the use of SEAs for all cancer sites and the exclusion of cancer deaths of persons under 20 years of age. With the addition of the time trend maps, it is now possible to identify areas which deserve further study by virtue of recent elevations and/or upward trends in cancer mortality.

The reader must be mindful of the limitations of this mortality survey as an epidemiologic pointer to studies of cancer etiology. In some instances the assumption of consistency of diagnosis, treatment, and death certification practices across place and time may not be justified. For example, a comparison of cause of death as coded on the death certificate with the diagnosis on hospital records⁹⁶ showed a high rate of discrepancies for colon and rectal cancer. As noted earlier, changes in ICD coding practices over time for several cancer sites also may have affected the patterns noted. Finally, certain cancers may be over-reported on death certificates, as suggested by the finding in some cancer registry areas that liver cancer mortality rates were higher than the corresponding incidence rates.⁹⁷ Patterns of mortality for cancers that are rapidly progressive and almost certainly fatal should most accurately reflect patterns of incidence, while the maps are less informative for cancers with favorable survival rates or problems in classification.

Despite the limitations of these data, it is clear from previous experience that the maps for certain malignancies have prompted analytic investigations that clarified associations with environmental and lifestyle hazards. The updated static and dynamic maps presented in this volume should enhance the utility of cancer mapping as an epidemiologic resource that facilitates research into the origins and eventual control of cancer.

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TESTIMONY OF
DR. JOHN F. MCCARTHY
DIRECTOR OF SCIENTIFIC AFFAIRS
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Before the Subcommittee on
Department Operations, Research and Foreign Agriculture
Committee on Agriculture
United States House of Representatives

July 28, 1988

Mr. Chairman, I am grateful for the opportunity to testify today, on behalf of the National Agricultural Chemicals Association (NACA)*, on H.R.4937, the "Pesticide Food Safety Act of 1988." Our members have a vital interest in this legislation and look forward to working with you as your Subcommittee examines proposals to address inconsistencies in EPA's legal authority in this area.

Mr. Chairman, we must solve the inconsistencies in our food safety laws. As the National Academy of Sciences reported in "Regulating Pesticides in Food — the Delaney Paradox", — it makes no sense to have a dual standard for raw and processed foods and for old and new pesticides which have been found to have an oncogenic response in laboratory animals. From day one, we have consistently supported the basic recommendation contained in the NAS report: Specifically, the concept of negligible risk applied across the board for raw and

The National Agricultural Chemicals Association (NACA) is a nonprofit, trade organization of manufacturers and formulators of pest control products employed in agricultural production. NACA's membership is composed of the companies which produce and sell virtually all of the technical crop protection materials (active ingredients) and a large percentage of the formulated products registered for use in the United States.

processed foods for pesticides where there is evidence of an oncogenic response in animal tests. We have also stressed, at the same time, the need for flexibility in the methodology for determining what constitutes a negligible risk. The process of risk assessment is complex. Not all animal oncogenicity data lend themselves to quantitative risk assessment. There have been significant advances in the science of chemical carcinogenicity in animals in recent years. Most experts now accept that all animal carcinogens are not necessarily human carcinogens. It depends on a number of factors. Likewise, substances which have been judged to present a carcinogenic hazard do not necessarily present a significant risk from exposure to low levels in the food supply. It's recognized that there are levels of exposure below which the risk is for practical purposes so low as to be essentially zero. Management of low risks can be evaluated through scientific judgement and common sense in many instances. On the other hand, there are situations where the information is more compelling and more quantitative treatment is appropriate.

Mr. Chairman, the proposed legislation as presented in Title II, provides not only a solution to the inconsistencies noted earlier, but provides the necessary flexibility to allow recent and future advancements in the science of risk assessment to be applied to the registration of pesticides on food crops. The authors are to be applauded for their approach. It is not only sound legislative policy, but it demonstrates trust and confidence in the science and the regulatory agencies.

In dealing with the establishment of food additive tolerances for pesticide residues, we have also stressed that the benefits of

pesticides should be considered. Here again, it makes no sense to have one part of the law consider benefits (408 tolerances on raw products) whereas another part of the law be strictly risk-based and ignore benefits (409 food additive tolerances). We believe your proposed legislation acknowledges benefits and goes a long way in straightening out this inconsistency.

Our bottom line is that we support Title II.

Turning now to other aspects of H.R.4937, we support Title I's straightforward and efficient treatment of pesticide reregistration. Here again, the reregistration issue has been of concern to us. We have long supported legislation to speed-up this process. We are concerned, however, about two aspects of the proposed provision. First, the legislation should insure that EPA be given sufficient resources to meet the deadlines. The time limiting factor has been, and will continue to be, Agency resources.

Second, the proposal's use of a registration denial hearing to challenge reregistration actions creates procedural changes which will cause unacceptable economic risks to the public. The amendment suggests a shift in the initial burden of proof from EPA to registrants. This subtle but important change is magnified when registrants, agricultural users, company stockholders, lenders and many others are faced with literally hundreds of millions of dollars of potential losses if reregistration is denied. Farmers and ranchers depend on existing products and may find few or no acceptable alternatives if EPA refuses to reregister the product. This consumer dependency and economic exposure is quite different from when a new

product's registration application is denied. We have provided language to your staff that will rectify this problem in the proposal.

Mr. Chairman, we would like to close our testimony with a few comments on Title III -- Integrated Pest Management (IPM). We share your support for advancing IPM technology through continued research. NACA has long supported IPM. It's a common sense approach to pest control. Namely, one should do all the "right" things to minimize pest infestations. Also implicit in IPM is that the crop should be monitored to determine if a pest control product is necessary to protect the crop from economic damage. We have long stated that pest control products should be used only when you need them. The days of "spraying by the calendar" are far behind us.

As a side note, we prefer the term Integrated Crop Management (ICM). One has to look at all aspects of producing a crop. Control of pests is one aspect. IPM, therefore, is a subset of ICM. We would like to share with you how the Illinois Cooperative Extension Service looks at this. We are submitting, as part of our testimony for the record, a 1984 publication from the Illinois Cooperative Extension Service entitled "Integrated Crop Management (ICM)". We would encourage members of the Subcommittee not only to read this and consult with the experts in the state of Illinois, but to also consult with experts in other states, especially those who have responsibility for the management of fruit and vegetable crops. We believe it is important we understand from those at the "grass roots" on the nature of the ICM and IPM issues and research needs.

NACA's initial reaction to Title III is this: We question the need to pass legislation on IPM without first hearing from the various

State Cooperative Extension Services and representatives of producers that such Federal legislation is necessary. On the other hand, we are not opposed to research programs which advance IPM techniques and refine the way in which our industry's products are used. So the issue is, how such research should be structured. It's not a case that nothing should be done, it's a question of how we should go about doing it. Certainly, if the answer is that it should be a Federally directed program, then it should be coordinated as stipulated in Title III. There have been too many Federal research programs that have been conducted in an uncoordinated manner. However, before proceeding further, we recommend the Subcommittee invite those who we identified earlier, to testify on Title III.

Thank you for this opportunity to testify on this important legislation. We look forward to working with the Subcommittee on this and other proposals needed to enhance public health protection and food production.



National Food Processors Association

1401 New York Ave., N.W.
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September 7, 1988

STATEMENT
of the
NATIONAL FOOD PROCESSORS ASSOCIATION
before the
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE
of the
HOUSE COMMITTEE ON AGRICULTURE
on
H.R. 4937
PESTICIDE FOOD SAFETY ACT OF 1988
presented by
Stephen G. Lodge
Assistant Director, Legislative Affairs

WASHINGTON, D.C.

• DUBLIN, CALIF.

• SEATTLE, WASH.

My name is Stephen G. Lodge. I am the Assistant Director, Legislative Affairs, for the National Food Processors Association. With me is Mr. Clausen Ely of Covington & Burling, counsel to the Association.

We appreciate the opportunity to appear today. Please keep in mind that the views that will be expressed have not yet been thoroughly discussed with the membership. Therefore, I ask that you keep in mind the fact that we will be continuing to refine our position on the bill as we hear more comments from our membership.

Before presenting our testimony, I would like to briefly describe the National Food Processors Association (NFPA). NFPA represents some 600 companies across the country, including most of the major food processing firms. Most of our members are involved with the processing of fruits, vegetables, meats, fish, and specialty products, and other members are involved in the manufacture of processing and packaging equipment and supplies. NFPA maintains and operates three food processing research laboratories where over 100 scientific personnel conduct studies on food safety, nutrients, and innovative technologies.

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Research conducted by our laboratories and others have shown that most pesticide residues that may be present in or on raw agricultural products are removed during food processing operations, such as peeling, washing, blanching, milling and other processing operations. Thus, the vast majority of processed foods actually consumed contain residues far below the levels that may be found on raw agricultural products.

We are pleased to support the following provisions of HR 4937:

Negligible Risk Standard - When the NAS report on the "Delaney Paradox" was issued in May of last year, we testified that we supported the basic concept of negligible risk and the application of negligible risk criteria to tolerances for pesticide residues in both raw and processed foods. We stressed, however, that appropriate consideration of benefits should also be retained. We reiterate that support today and are pleased that H.R. 4937 embodies a negligible risk standard and provides for continued consideration of benefits in setting pesticide tolerances. We are also pleased that the bill provides EPA with sufficient authority to determine specific levels associated with a negligible risk based on evolving scientific data and principles.

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It is important for agriculture, the food industry and the consuming public for the negligible risk standard to be embodied into legislation. While both the EPA and FDA have been informally using such a standard for a number of years under various terms, such as de minimus, some groups have challenged the use of the concept in the courts. In fact, EPA's response to the NAS report has been delayed primarily because the Agency does not have an existing legal framework within which to implement the recommendations contained in the report. We have confidence that these federal agencies will use this authority in a responsible manner to ensure that the public is not exposed to harmful levels of pesticide residues in the food supply.

Consistent Regulation of Foods - We support the principle expressed in the NAS report and embodied in this bill that the regulation of pesticide residues should be consistent for both fresh and processed foods. HR 4937 would accomplish this objective by regulating all foods under Section 408 of the FD&C Act. Pesticide residues in processed foods would no longer be regulated under the Delaney provision of Section 409. Importantly, the bill provides that all processed foods for which a tolerance has not been established would have the same tolerance as established for the raw agricultural commodity, unless EPA determined that a higher tolerance was necessary and such a higher tolerance was in place.

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Use of Actual Residue Data in Risk Assessments - When evaluating the relative risks of pesticide chemicals, the bill would require the use of actual pesticide use and residue data to the greatest extent possible. This is an extremely important provision. The NAS "Delaney Paradox" report is based on the erroneous assumption that all registered pesticides are used at the maximum application level and that they are present at the maximum residue level authorized by a tolerance. The use of real world pesticide use and residue data in risk assessments will result in more accurate and meaningful exposure assessments.

While we wholeheartedly support the above aspects of the bill, we believe that additional consideration should be given to the following issues:

Need for FDA Action Levels - We recommend that the bill be amended to provide clear authority for the FDA to be able to issue action levels for pesticides that are present in the environment from past use and which unavoidably result in residues in or on raw agricultural commodities and processed foods. An example is the need for action levels for DDT that is present at detectable levels in or on some foods as a result of exposure of the food to the environment.

Need for A Statutory Requirement that EPA Tolerances and FDA Action Levels Are Uniform Across the Country - We recommend that the bill be amended to provide that all interested parties, especially state public health officials, should participate fully in the EPA pesticide tolerance setting process, but that when the EPA issues a final tolerance or the FDA issues a final action level, that those rules become uniform across the country and may not be altered by state, county, or local governments. If a state, county or local government has information that the established tolerances or action levels are not protective of public health, then they should offer that information to the EPA or FDA officials for their review and consideration. The decision to revise the tolerance or action level should rest only with Federal officials. The food industry needs a national system of uniform pesticide tolerances and action levels to effectively and efficiently market its products.

Evaluation of Pesticide Effectiveness and Cost - Where EPA is required to evaluate the risks of an alternative pesticide having risks greater than an existing pesticide, the Agency should also be required to assess the effectiveness and cost of the alternative as well as the actual usage and residue data.

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Registration and Reregistration of Pesticides - We recommend that aspects of the bill concerning the registration and reregistration of pesticides be considered in the overall context of the reauthorization of FIFRA. The amendments to the FD&C Act proposed in HR 4937 are important and deserve consideration on their own merits.

Integrated Pest Management - The proposed IPM initiative is laudable and can be supported by the agricultural community. In fact, many NFPA members are working with their growers to implement cost effective IPM programs that result in reduced pesticide usage.

International Marketplace - The National Food Processors Association has a long standing policy of working to ensure equal treatment for domestic food processors operating in the international marketplace. The issue of pesticide regulation is one where there is potential for conflict between domestic and foreign laws. We support the need for vigorous enforcement of pesticide laws on both domestic and foreign producers. If US based firms are forced to comply with stricter standards than are their international competitors, they will be placed at a serious economic disadvantage. We ask that you keep this potential problem in mind as you work on this and other legislation in the pesticide area.

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Summary and Conclusions - We commend the work of Congressman Roberts and this subcommittee to develop a meaningful bill to address the pesticide tolerance issues presented in the NAS report. We support the provisions of the bill which:

- * embody application of the negligible risk standard with consideration of benefits in setting pesticide tolerances;
- * provide for consistent regulation of foods under section 408 of the Act; and
- * provide for the use of actual residue data to the greatest extent possible in the evaluation of the relative risks of pesticides.

However, we believe that the bill could be improved by providing:

- * clear authority for FDA to issue action levels for levels of pesticide residues that are unavoidably present due to their presence in the environment;
- * a statutory requirement for EPA Tolerances and FDA action levels to be uniform across the country; and
- * that pesticide registration and reregistration issues be omitted in favor of consideration in the overall context of FIFRA reauthorization.

As we stated at the outset of our statement, we will be working with our members over the coming weeks to further develop and refine our views and positions on the bill. We will keep you informed if any of our policies or positions change as a result of our continuing discussions with our members.

We appreciate this opportunity to present our comments and would be pleased to respond to any questions.

* * * * *



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STATEMENT OF
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on H.R. 4937, THE PESTICIDE FOOD SAFETY ACT OF 1988
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS RESEARCH AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES
SEPTEMBER 7, 1988

Mr. Chairman and Members of the Subcommittee, the National Audubon Society appreciates this opportunity to testify on H.R. 4937, the Pesticide Food Safety Act of 1988. Your attention to the safety of our food supplies is extremely welcome, and we would like to work on this issue with your committee and the Energy and Commerce Committee, to which H.R. 4937 has also been referred.

Your attention to the food safety issue is very timely. National polls taken in December 1987 and January 1988 by Roper Associates found that 86 percent of the American public viewed pesticide residues as a "very serious" or "somewhat serious" problem. The Food Marketing Institute survey indicated that 75 percent of American consumers view pesticide residues as a "serious health hazard." The fact that more consumers are going out of their way to find and purchase organically grown or pesticide-free foods is another trend that indicates increased public concern about the quality of our food. In addition, some states such as California are seeking to protect their citizens more proactively because of growing mistrust in the Federal government's ability to do so. Accordingly, efforts to bring together aspects of the National Academy of Sciences report criticizing EPA's tolerance-setting process with new initiatives for integrated pest management (IPM) are appropriate.

One of the most important findings of the NAS report is the inconsistency of current law respecting raw and processed food, and old and new chemicals. The report concluded that if just these inconsistencies could be replaced by a meaningful negligible risk standard for pesticides posing cancer risks, the high percent of carcinogens now in our food supply could be dramatically reduced. But it is unclear to us how H.R. 4937 would immediately or even very soon reduce the carcinogens now in our food supply when it would delete the Delaney Clause and provide registrants with twelve years to put together a complete dataset for each untested chemical, require rapid review by EPA once application is submitted, allow indefinite time for data gaps to be filled, and fail to provide a fee structure to pay for quick review.

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Our comments on individual sections follow:

TITLE I -- PESTICIDE REGISTRATION

Sec. 102. REREGISTRATION OF PESTICIDES

H.R. 4937 would mandate EPA to review data "as expeditiously as possible," but no longer than one year after date of submission of "a complete application for reregistration." No provision for fees to recover the cost of this fast track reregistration is provided, thus, implementation of such a rapid reregistration scheme would amount to automatic reregistration.

In contrast, registrants are provided with 12-year registrations before reregistration requirements are imposed. In 12 years, a great deal could happen to alter regulatory needs, indicate actual fate in the environment, or reflect scientific advances. Inexplicably, conditional registrations are granted registration rights, labeled "functional equivalent of registration." The purpose of conditional registration in 1978 was to allow registrants time to generate the required data without penalty of being on the wrong end of the time sequence, i.e., before 1978 when less stringent requirements were in force. It is not clear why conditional registrations should have "functional equivalent registration" rights of 12 year duration. If anything, the process of approving conditional registrations should be reevaluated.

While imposing a stringent one-year action frame for EPA evaluation, H.R. 4937 would require EPA to allow registrants "sufficient time" to obtain "any requested additional information." "Sufficient time" is not defined, with the clear implication that the registrants keep products on the market for whatever "time it takes to comply with requests for data." The 1978 FIFRA amendments gave EPA authority to suspend a registration if additional data has not been submitted "within the time required by the Administrator," and appropriate steps to "secure data" have not been undertaken. H.R. 4937 seems to make reregistration immune to alteration once on the market.

In addition, it seems H.R. 4937 would give registrants who failed to comply with data requirements Section 6 cancellation rights with full privileges such as 360-day adjudicatory hearings rather than 75 days as under current law. Because hearings are already too long and too complicated, there is a need to simplify proceedings, not unduly protract them.

We also question the need for an additional definition of "unreasonable adverse effect" to cover the consumer impact [(h) Food Use Pesticides]. The current definition of unreasonable adverse effects takes into account "the economic, social, and environmental costs and benefits of the use of any pesticide." Consumer impact is implicit in all three: economic, social and environmental.

Section 103 CANCELLATION

Existing stocks -- Although FIFRA provides for use of existing stocks of canceled pesticides for conditional registrations under Sec. 6(e)(2) and under Sec. 19(c) for disposal of pesticides, such a provision does not belong in a food safety bill. The issue of existing stocks is a contentious one, the use of which has resulted in contamination of food by canceled pesticides such as aldrin/dieldrin and chlordane/heptachlor. In the case of aldrin/dieldrin, EPA allowed existing stocks to be used up because the agency thought it would take more time to figure out distribution channels than allow approximately 5 percent of the total 1974 stocks to be used up in 1975. A similar argument was applied when EPA allowed existing stocks of the suspended product chlordane/heptachlor, to be used up over several years instead of having continued production and use while adjudicatory hearings proceeded.

Use of existing stocks of heptachlor resulted in contamination of milk supplies from cows fed heptachlor-tainted feed. Milk in Arkansas, Missouri, Kansas and Oklahoma had to be seized. As for Dieldrin, some farmers hoarded stocks to use after the suspension. Mysterious residues long after the suspension in 1975 have confounded monitoring in many places. These examples serve to illustrate some of the hazards involved in using existing stocks of canceled and suspended pesticides. If a pesticide is dangerous enough to constitute an imminent health threat, it is too dangerous to be allowed to make its way through the channels of trade. Such stocks should be recalled and disposed of as hazardous waste.

TITLE II Pesticide Residues

Section 204. TOLERANCES FOR PESTICIDE CHEMICALS

The National Audubon Society believes that no detectable level of carcinogenic pesticide residues is toxicologically insignificant to humans. We believe that the presence of carcinogens in our food and water should not be accepted as inevitable or necessary. The fact that carcinogens are in our food and water supplies does not mean they should be legally sanctioned as "negligible" or "acceptable." We support negligible risk under carefully prescribed circumstances, with specific limits and criteria, and only if "negligible risk" actually reduces the load of carcinogens in food and water, and eventually helps to bring the total aggregate of carcinogenic pesticides down to a negligible risk.

Unfortunately, the provision for negligible risk provided in H.R. 4739 is vague, ambiguous and open-ended. What is "associated" with a negligible risk? An opinion certifying "usefulness" is overly broad for a "benefits" case. Even on the risk side, "prudent" and "associated with a negligible risk" are not defined. Would the actual presence of residues "justify" establishment of a level above zero. How is "actual usage of the pesticide chemicals" to be collected and verified? Are reports to be compiled by a governmental entity? Are there to be spot checks? Is there provision for monitoring? Enforcement mechanisms are needed to ensure that risk levels are not exceeded.

Finally, to establish a protective and defensible negligible risk standard, dietary exposure to a pesticide chemical or pesticide chemical residue must include other known sources of dietary exposure such as drinking water and consideration for health risks of identifiable population groups that may suffer higher than average risk such as the old and/or chronically ill.

TITLE III -- INTEGRATED PEST MANAGEMENT

Audubon is pleased that H.R. 4937 has devoted a title to integrated pest management. IPM and low input technologies can surely help to reduce the quantities of pesticides used on crops, and therefore, lower residues on food. There is an institutional incentive to increase the quantities of pesticides applied, on each acre, each year, simply to increase yields. Today's high input costs, low market prices, and pesticide contamination of food and water supplies demand that we act to reduce inputs and the incentives to apply more and more agricultural chemicals. Increased chemical use increases supplies which translate to reduced profits for farmers, and it also increases the likelihood of water and food contamination. There is no doubt that IPM, biological controls, cultural and mechanical techniques can increase the diversity of technologies (not just chemicals) needed for crop production on all crops, and help address the problems of increased chemical use.

We are encouraged with the provision for extending coverage under the Federal Crop Insurance Program to cover pest losses suffered by farmers employing recommended IPM techniques. This is the type of encouragement that is needed to bring about more IPM advisers and more subscribers to IPM programs.

At the same time, we would like to know why the new IPM initiative is limited to minor crops. What is the criteria for "minor" and "major" crops? Apples and citrus constitute a large proportion of the average daily diet as well as acres in production, and they are considered major crops. Authorization and appropriation of \$25 million per year for 6 years could do a great deal for IPM on major and minor crops, as well as low-input technologies. In one example, biocontrols which should be included in IPM programs, have produced greater savings for citrus. The introduction of a parasite of the snow scale in Florida citrus was so effective it saved about \$8 to \$10 million annually (in 1975 dollars) in the cost of insecticides not needed after use of the parasite. Such savings are vital for all farmers. We agree that minor crops have been neglected, but why reserve IPM funds for only minor crops?

In regard to finding number (4) Integrated pest management (IPM) systems, we would suggest the following underlined sections in Section 1440 and strike ():

"...including those that will incorporate new and traditional plant diseases, weed, nematode and insect control techniques drawing on genetic engineering, biotechnology, biocontrol, use of improved and more efficient varieties, and cultural practices offer great promise for (managing) better management of fertilizer, water and pesticides. Such techniques can reduce pesticide residues and contribute (ing) to a diversity of (pesticide) tools for crop production (minor use groups)."

These additions are intended to be more inclusive of other pests and other strategies, not just chemicals. IFM has been used to justify keeping carcinogenic pesticides on the market with no reduction in exposure. If such pesticides are to be used in an IFM program, there should be a plan developed whereby use is prescribed by trained and responsible experts, and monitoring integrated into the plan to assure the public that residues do not exceed specified levels.

CONCLUSION

Mr. Chairman and members of the subcommittee, the risk from the substantial number of pesticides posing a carcinogenic threat in our food and water supplies is unacceptable. A breakthrough is urgently needed. There is a clear and compelling need for procedures to reduce progressively this risk. While H.R. 4937 has parts of such procedures, it does not create a system to accomplish a progressive reduction of carcinogenic pesticide residues in food, to remedy the delay in filling the data gaps which exist for over half of the pesticides now in our food, or to provide sorely needed agency resources.

H.R. 4937 has addressed new issues such as a coordinating committee to examine minor uses of pesticides and IFM, and attempted to incorporate conclusions of the National Academy of Sciences Report on Regulating Pesticides in Food. It does not appear to us, however, that H.R. 4937 addresses the basic problems Audubon members have with the quality of our food and water. Audubon members continue to have a profound lack of confidence in the government to regulate effectively. They mistrust the companies who produce pesticides that have come to contaminate food and water. We need evidence that legislation will improve the regulatory picture, not undermine or cloud it. Without resolution, public confidence continues to erode, as does the patience of the voting public.

Thank you.



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TESTIMONY
OF
JANET S. HATHAWAY
ON BEHALF OF THE
NATURAL RESOURCES DEFENSE COUNCIL (NRDC)

BEFORE THE
COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH
AND FOREIGN AGRICULTURE
OF THE
U. S. HOUSE OF REPRESENTATIVES

CONCERNING H.R. 4937
THE PESTICIDE FOOD SAFETY ACT OF 1988

SEPTEMBER 7, 1988

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I.	CURRENT LAW DOES NOT PROVIDE ADEQUATE PUBLIC HEALTH PROTECTION FROM PESTICIDES IN FOOD.	1
II.	H.R. 4937 DOES NOT ENSURE ENHANCED PROTECTION OF OUR FOOD SUPPLY.	4
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Thank you for the opportunity to testify before this Subcommittee on H.R. 4937, the Pesticide Food Safety Act of 1988. I am Janet Hathaway, Senior Project Attorney with the Natural Resources Defense Council (NRDC). NRDC is a nonprofit, public interest organization dedicated to protecting public health and the environment through scientific research and legal advocacy.

I. CURRENT LAW DOES NOT PROVIDE ADEQUATE PUBLIC HEALTH PROTECTION FROM PESTICIDES IN FOOD.

NRDC has released a new book entitled Pesticide Alert¹, presented testimony before this and other Congressional committees, and issued reports documenting serious flaws in our regulations and laws concerning pesticides. We have identified many inadequacies in the government program to protect food from pesticide residues. As you know, NRDC has been working closely with the Agriculture Committee in the effort to reform the regulation of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). We have also sought improvements to the Federal Food, Drug and Cosmetic Act (FDCA), the law that governs pesticide residues in food. Among the many serious deficiencies of our federal program to protect the public from pesticides in food are the following:

¹ Lawrie Mott and Karen Snyder, Natural Resources Defense Council, Pesticide Alert: A Guide to Pesticides in Fruits and Vegetables, 1988.

***EPA has incomplete or inadequate toxicological and residue chemistry data for many of the nearly 300 pesticide active ingredients used in or on food. The legal limits for residues of pesticides remaining in food (or "tolerances") were established for many pesticides before the Agency had information on the long-term effects of dietary exposure. When EPA receives new data on carcinogenicity, the potential to cause birth defects, effects on reproduction, or other deleterious consequences, EPA does not rapidly reassess and revise tolerances to reflect the best available safety data.

***Ingredients which do not kill, repel or control pests, misleadingly termed "inert" ingredients, are not adequately regulated, although many may cause equally serious adverse effects as "active" ingredients.

***EPA lacks authority to act immediately to modify or revoke tolerances even when new information indicates an extreme risk to public health.

***EPA grants tolerances for pesticides even in the absence of a practical analytic method for measuring the residues in foods. The agencies which enforce tolerances, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), are forced by their limited equipment and resources to rely almost exclusively on multi-residue analytical methods. The agencies are unable to detect nearly half of the pesticides for which EPA has set tolerances using multi-residue methods.

***EPA has interpreted the FDCA to condone the presence of carcinogenic pesticides in raw food and in certain processed foods. EPA has argued that a risk-benefit analysis is appropriate for determining when carcinogenic pesticides can be used on raw foods.

***EPA invokes the Delaney clause infrequently, and never with respect to pesticides which have been on the market for many years. Old pesticides pose some of the greatest dietary hazards, but EPA allows the continued, wide-spread use of carcinogenic pesticides in food.

Each of these problems need to be addressed by legislation to improve public health protection from pesticides in food. Unfortunately, H.R. 4937 does not contain sufficient safeguards to ensure that the many impediments to a safe and rational pesticide program are addressed and that food safety is enhanced.

After close examination of H.R. 4937, NRDC has concluded that we cannot endorse the bill. H.R. 4937 grants the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) broad discretion which could be used to better protect our food supply from carcinogenic and otherwise hazardous pesticides. However, neither FDA nor EPA have wisely used the broad discretionary authority they currently enjoy to adequately protect the public from pesticides in food. Often ambiguities in statutory language have been exploited to condone current practices, even when those practices pose a clear hazard to the public health. The histories of both EPA and FDA provide

us with ample evidence that food safety is often compromised even when statutory mandates are clear and unequivocal. Both agencies' neglect of the explicit prohibitions in the Delaney clause demonstrates an unwillingness to tighten or eliminate certain uses of pesticides even when they are both hazardous and clearly illegal.

II. H.R. 4937 DOES NOT ENSURE ENHANCED PROTECTION OF OUR FOOD SUPPLY.

A. THE REREGISTRATION PROVISIONS DO NOT INCLUDE DEADLINES NEEDED TO ENSURE THAT ALL PESTICIDES ARE REEVALUATED IN THE NEXT NINE YEARS.

NRDC strongly supports accelerated reregistration of pesticides which were licensed for use without complete data on health and environmental effects. In the 99th Congress, NRDC was one of the principal groups involved in negotiations with the National Agricultural Chemicals Association (NACA) which lead to a detailed reregistration schedule, now incorporated in H.R. 2463 and S. 1516. We continue to strongly support the reregistration provisions of H.R. 2463 which were recently adopted by this subcommittee and which are expected to be brought before the full Committee soon.²

² The DORFA Subcommittee reported FIFRA amendments, including the reregistration provisions supported by NRDC, on July 13, 1988.

NRDC does not endorse the reregistration section of H.R. 4937. We believe that the provision is insufficient to ensure a rapid and orderly reregistration of all pesticides which still lack complete data.

NRDC believes that reregistration should occur more quickly than is anticipated by the drafters of H.R. 4937. It should take registrants no more than four to five years to generate even the most complex data, and most tests can be completed and analyzed in less than two years. H.R. 2463 requires EPA to complete the reregistration of all pesticides within the next nine years. Such a schedule can be achieved and should not be extended.

H.R. 4937 requires registrants to submit a "complete application for reregistration" within eleven years. The bill does not identify the components of a complete application. H.R. 4937 also enables EPA to require additional data for pesticides and requires EPA to "permit sufficient time for applicants to obtain any requested additional information." The bill sets no interim timetables for registrants to submit easily obtained data or for EPA to evaluate the data and determine whether the pesticide should be permitted to continue in use. The bill does not explicitly state whether failure to comply with the data submission deadlines results in automatic rejection of the reregistration application or revocation of existing food tolerances. In the absence of an explicit provision, it appears that registrants may not respect deadlines, and deadlines may be difficult to enforce.

In addition, the reregistration schedule of H.R. 4937 may be problematic to administer. H.R. 4937 is almost guaranteed to result in huge quantities of data submissions at the very end of the 11-year period, making it extremely unlikely that EPA will be able to review and evaluate all data within an additional year, as required by the bill. The consequence of EPA's failure to live to the timetable is unclear, and may lead some registrants to argue that their pesticide should be presumed reregistered, even in the absence of an Agency determination. Confusion and litigation is sure to result. A preferable approach would require some short-term test results to be submitted soon and would spread data submission deadlines over the next two to six years. This alternative would avoid suddenly swamping the Agency with more data than it can possibly carefully examine.

Reregistration and reassessment of old pesticide tolerances are both desperately needed. Currently, petitioners must submit adequate data to support new tolerances. But EPA's process for obtaining data for already-registered pesticides is far less systematic. Although EPA has initiated chronic toxicity data call-ins for most food use pesticides³, most of these pesticides are missing some crucial data, particularly in the area of residue chemistry. These data gaps have resulted in regulatory paralysis.

³ Testimony of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, Regulation of Pesticide Hearing, House Energy and Commerce Committee, June 8, 1987, p. 178. Also see 49 Federal Register 49544, December 20, 1984.

To illustrate this persistent problem, the Committee should consider the case of the EBDCs, the most widely-used group of fungicides registered in the United States. Both EPA's decision documents and the recent NAS Delaney report indicate high cancer risks for this class of fungicides.⁴ The EBDC fungicides were registered in 1966 and 1967, and a special review of the cancer risks of the compounds began in 1977. In 1982 regulatory action was deferred in part because of incomplete information on exposure to the carcinogenic breakdown product, ETU. NRDC sued the agency, and we reached a settlement with EPA in 1984 when the Agency agreed to demand new data and to reassess the chemical before December 31, 1986. Registrants of these fungicides failed to comply with EPA's deadlines for submitting data. EPA now expects not to receive complete data until mid-1989.⁵

The case of the EBDCs is not unique. GAO reports that only approximately 50% of registrants submit EPA-requested data on old chemicals on time.⁶ EPA Assistant Administrator John A. Moore testified before the Energy and Commerce Committee that under

⁴ EPA's decision documents indicate a lifetime dietary cancer risk of up to 4.9×10^{-6} (1 cancer in 2,000 persons exposed). NAS estimates for each of four EBDCs was similar. NAS, *supra*, p. 68.

⁵ Testimony of Dr. John A. Moore, *supra*, pp. 151-153.

⁶ "Data supplied by EPA from the [data call-in] tracking system indicate that about 47 percent of registrant responses to active ingredient data requirements (i.e., chronic toxicity data on the active ingredient) were overdue." General Accounting Office, *Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks*, GAO/RCED-86-125, April 1986, p. 40.

current authorities, EPA's revocation of a tolerance due to a registrant's failure to submit data promptly is labor-intensive and time-consuming. He suggested that revocation, when challenged by registrants, may take years.⁷ Dr. Moore expressed the need for a provision in the law automatically revoking tolerances where data-submission deadlines are missed.⁸ NRDC believes that food safety legislation should contain provisions automatically revoking tolerances if required data are not submitted in accordance with statutorily-defined deadlines.

B. H.R. 4937 WOULD NOT ESTABLISH A STRICTLY HEALTH-BASED STANDARD FOR REGULATING PESTICIDES IN ALL FOODS.

A central feature of this bill is the establishment of a new standard for the regulation of pesticides in food. H.R. 4937 would require EPA to use one standard for regulating pesticides in both raw foods and processed foods. Unfortunately, NRDC does not believe the new standard will improve public health protection from carcinogenic and otherwise dangerous pesticide residues.

The new standard would govern pesticide tolerances only for substances "not general recognized, among experts qualified by scientific training and experience to evaluate the safety of

⁷ Testimony of John A. Moore, June 8, 1987, HRDA, p. 172.

⁸ Testimony of John A. Moore, June 8, 1987, HRDA, p. 178.

pesticide chemicals, as safe for use."⁹ This provision effectively creates a new GRAS ("generally recognized as safe") exception to section 408. NRDC opposes any such new exception. Historically, Agency assumptions about which substances were biologically benign have frequently proven erroneous. Because data gaps remain for many pesticides registered before 1972, a new GRAS exception could be abused by EPA as a loophole to retain uses of pesticides lacking data to clearly prove their safety or dangers. The absence of good data showing hazard should not be equated with reliable data proving safety. NRDC believes that tolerance levels should be set for all pesticide residues, unless the residues have been thoroughly tested and have been found to cause no adverse biological effects in any organism or to present no risk to human health, including to identifiable population groups with greater sensitivity or greater exposure, at all levels of exposure. If the substances are truly safe, EPA should have no difficulty establishing a protective tolerance level, based on adequately toxicology and residue chemistry data. An additional exception for GRAS is unnecessary, and because GRAS is left undefined, it is subject to abuse.

When tolerances are required, the standard for EPA tolerance-setting under H.R. 4937 is governed by the phrase "to the extent necessary to protect the public health." This phrase is currently part of the section 408 standard and has been

⁹ H.R. 4937, section 204(e), amending FDCA § 408(b)(1).

interpreted in vastly divergent ways. FDA interprets the section 408 general safety clause as permitting the use of carcinogens, so long as the risk from each individual chemical is not greater than 1×10^{-6} , or one cancer in a million persons exposed over a lifetime.¹⁰ EPA reads the section 408 obligation to set pesticide tolerances "to the extent necessary to protect the public health" as granting the Agency broad discretion. EPA argues that section 408 is a risk-benefit standard, comparable to the standard for eliminating uses of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).¹¹ The Agency believes that even levels of carcinogenic pesticides causing more than one cancer from lifetime exposure of one million people can be lawful, so long as EPA identifies benefits which EPA determines "outweigh" the risks. Others, including public interest organizations, interpret section 408 to require EPA to limit pesticide residues to safe levels, and to prohibit the food uses of pesticides--such as carcinogens--which pose risks at all detectible levels.¹² To amend the FDCA while continuing the use of the controversial phrase "to the extent necessary to protect

¹⁰ NAS, *supra*, p. 94.

¹¹ Testimony of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substance, EPA, Regulation of Pesticides Hearing, House Energy and Commerce Committee, June 8, 1987, p. 170.

¹² One court is now being asked to decide whether section 408 mandates that EPA prohibit all residues of the carcinogenic pesticide daminozide (Alar). See Nader v. EPA, No. 87-7103, (9th Cir., filed June 18, 1987).

the public health" will only continue the confusion about how this law should be implemented.

C. H.R. 4937 SETS A "NEGLECTIBLE RISK" STANDARD FOR HOW MUCH PESTICIDE RESIDUE MAY REMAIN IN OUR FOODS.

H.R. 4937 creates a "negligible risk" standard for oncogenic pesticides.¹³ NRDC considers this "negligible risk" standard for carcinogenic pesticides objectionable for three reasons.

First, the negligible risk standard is qualified by requiring EPA to "give appropriate consideration to the risks and benefits" of setting the tolerance. This effort to import a risk-benefit standard into the Food, Drug and Cosmetic Act will be vigorously opposed by NRDC. NRDC believes that the risk-benefit standard will be interpreted by the EPA as a grant of authority to set pesticide residue tolerances at levels which pose hazards. To enable EPA to set tolerances at levels posing hazards whenever they cite some benefits of the pesticide is a perversion of the purpose of the FDCA. The FDCA was created to ensure that hazardous substances would be incorporated into our food supply only if they were both unavoidable and truly safe. Benefits to the pesticide industry, or to the food industry, cannot cancel out real dangers for consumers.

EPA currently interprets FDCA section 408 as enabling the Agency to balance the risks of pesticide with the benefits of the

¹³ *Id.*, section 204(e), amending FDCA section 408(b)(1).

chemical.¹⁴ NRDC believes such an interpretation is unsupported by the statute, legislative history, or legal precedents. The history of EPA's implementation of the FIFRA statute demonstrates that benefits considerations can become an enormous loophole to the strict regulation of widely-used but extremely dangerous pesticides. EPA has repeatedly cited benefits to growers to attempt to justify the use of pesticides posing very significant risks to workers and the public. The benefits and risks of pesticide use are often difficult to quantify. Benefits estimates are often inflated by Agency acceptance of unsubstantiated claims that yields would plummet if alternative chemical or cultural practices were employed.

Second, H.R. 4937's "negligible risk" standard for carcinogenic pesticide residues is insufficient to constrain EPA from asserting that high cancer risks, such as risks exceeding one in a million, are "negligible." NRDC is concerned that the vagueness of the mandate to EPA to set tolerances which present no more than a negligible risk could lead courts reviewing EPA standards to defer to virtually any Agency claim concerning acceptability of risks. Instead of requiring more protective standard-setting, this provision could insulate EPA tolerances which result in high risks to some portions of the population. NRDC believes that EPA should never be allowed to consider as

¹⁴ Testimony of John A. Moore, June 8, 1987, supra, p. 170.

"negligible" any risk of cancer or other serious disease which exceeds a rate of one in a population of one million.

Third, the bill does not identify what level of exposure to non-oncogens is to be deemed safe. Most non-oncogenic effects are believed to occur only above a certain concentration, which is called the "threshold." The Agency practice for new pesticides is to establish a "no adverse effects level" (NOEL) for each non-oncogen and to ensure residues do not exceed the NOEL. NRDC believes these substances causing birth defects, neurological damage or other health problems should never be allowed in our diets in concentration approaching the NOEL. Normally, a large margin of safety should be provided, to protect people who may be far more sensitive to the effects of hazardous pesticides than laboratory animals. In no case should dietary concentrations of pesticides exceed 1% of the no adverse effects level (NOEL) identified through laboratory experiments.

D. H.R. 4937 ALLOWS TOLERANCES TO BE SET AT DANGEROUSLY HIGH LEVELS.

NRDC believe that the food supply should bear no pesticide residues which are unsafe. If this bill were designed to rapidly phase out high risks, the bill could justifiably contain a provision for a very short transition period during which risks would be lessened, but still remain significant. But the bill does not demand or assure risk reduction and gives broad discretion to EPA to permit risky pesticides to remain in our

food supply. Therefore NRDC must strenuously oppose the provision which enables EPA to set tolerances posing greater than a negligible risk. This "exception" will become a loophole of enormous proportions, particularly because the bill gives EPA virtually unlimited power to declare risks negligible.

E. NRDC BELIEVES OTHER PROVISIONS MUST BE INCORPORATED IN H.R. 4937 TO ACHIEVE A SAFE FOOD SUPPLY.

NRDC believes a purely health-based standard can effectively protect the public from dangerous pesticides in our food supply only if Congress insists on explicit, legislative mandates constraining EPA's ability to approve tolerances for such substances. In no case would NRDC support a bill which granted EPA unlimited discretion in determining what constitutes "negligible risk." A supportable food safety bill must establish conservative, health-protective principles which the bill requires EPA to incorporate into its analysis of dietary exposure and risk. Any weakening of such principles will assuredly result in a regulatory scheme riddled with loopholes, and potentially, a food supply loaded with carcinogens and other dangerous substances. NRDC believes that strict prescriptions for exposure and risk assessment are prerequisites of food safety legislation which in fact will reduce pesticide risks.

1. Tolerances should be set at safe levels. Tolerances must be safe for sensitive population subgroups with special

diets, including children. Tolerances should be established only if the risk from the pesticide is negligible to all population subgroups, including people with special food consumption patterns. Many of our existing tolerances were based on the assumption that everyone eats the "average" diet. For example, EPA set tolerances based on an assumption that no one consumes more than 7.5 ounces per year of avocado, artichokes, melon, eggplant, or nectarines. In fact, many individuals eat more than 100 times the amount of apples, oranges and other commodities consumed by the statistically "average" consumer. An improved food safety law should require EPA to correct these inappropriate dietary assumptions.

H.R. 4937 should also demand an essential measure of protection for people who may be especially vulnerable to dietary risks, including infants, children, and the elderly. EPA has data indicating that infants and children may be the group most exposed to many foods and to the pesticide residues they contain. For example, EPA's Tolerance Assessment System indicates that, based on 1977 consumption data, the average toddler consumes per unit of body weight 16 times more milk products, 11 times more fresh bananas, 10 times more peanut butter, and 6 times more apples than typical adult women.¹⁵ There is reason to believe that infants and children also may be more susceptible to

¹⁵ Testimony of Lawrie Mott, NRDC, Regulation of Pesticides, Hearing Before the Subcommittee on Health and Environment, House Energy and Commerce Committee, June 8, 1987, pp. 77-78.

carcinogens because of their rapid rate of cell division and their incompletely developed immune systems. Therefore, this bill should require EPA to identify population subgroups with special diets, including infants and children, and to set tolerances that ensure that they are not exposed to significant dietary risks from pesticides.

2. Exposure must be calculated at the tolerance level.

It is essential that Congress require EPA to calculate exposure to pesticides based on the legally-enforceable residue limits: the tolerances. Without such a requirement, EPA is certain to underestimate exposures received by many consumers. The tolerance level should be the level at which exposures are calculated for four major reasons. First, as a policy matter, EPA should ensure that the food supply is safe for everyone who eats produce with legal concentrations of pesticide residues. Most of us have no way to determine the residue level in the apple we eat for lunch, and we should be assured that every legal apple is in fact a safe apple. Children, the elderly and others with particular sensitivities to the effects of dangerous pesticides should be protected by the tolerance.

Second, FDA's monitoring program indicates that two to four percent of domestic foods tested are found to have illegal

pesticide residues.¹⁶ Most of those fruits and vegetables containing illegal concentrations of pesticides are consumed by an unwary public.¹⁷ Therefore, exposure calculations at tolerance levels are sometimes even lower than the actual dietary exposures of individuals who inadvertently consume excessively-treated produce.

Third, requiring EPA to calculate exposures at the legal limit provides an incentive for those who seek a pesticide tolerance to minimize pesticide residues. If the tolerance level poses a significant risk, those who wish to continue the use of a pesticide on food should be required to meet a lower, more protective tolerance. Actual data indicating the range of pesticide residue levels resulting from legal application should be used for calculating exposure only if EPA has reliable data on actual residues and establishes a new tolerance at the actual residue level.

¹⁶ Between FY 1979 and FY 1985, the percent of domestic food samples containing illegal pesticide residues ranged from 1.8 percent to 4.2 percent. General Accounting Office, Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues, October 1986, p. 25. During these same years, the violation rate for imported food ranged from a low of 4.7 percent to a high of 8.2 percent. General Accounting Office, Pesticides: Better Sampling and Enforcement Needed on Imported Foods, GAO/RCED-86-219, September 1986, p. 23.

¹⁷ GAO found that at least 60 percent (52 of 87) of spot-checked food shipments determined to violate pesticide residue limits in FY 1985 were not recovered by FDA. General Accounting Office, Pesticides: Better Sampling and Enforcement Needed on Imported Foods, GAO/RCED-86-219, September 1986, p. 43.

Fourth, farm practices--including less frequent application, lower rates of application and longer pre-harvest intervals--can

offer greatly reduced residue levels. Lower legal limits on pesticide residues will encourage more sparing, thoughtful use of pesticides and will reward growers who employ integrated pest management (IPM) practices. Lower tolerances--if adequately enforced--benefit consumers. In addition, minimizing pesticide use will also limit damage to natural resources such as ground water and reduce growers' pesticide expenditures.

3. EPA's exposure assessments must calculate exposures to pesticides in all commodities and in drinking water.

EPA ordinarily assesses and regulates risks in an exceptionally fragmentary way. EPA normally proceeds chemical-by-chemical, considering each medium of exposure separately. For example, when setting limits on carcinogens in air, EPA does not usually consider exposures to the same substance which may occur through water, soil, skin absorption or diet. This bill unfortunately continues the tradition of chemical-by-chemical analysis. At a minimum, the bill should require EPA to calculate exposure by considering all exposures to a pesticide, both through the diet and through likely exposures to consumer and household products. Many consumers use the same pesticides that are used in agriculture in their homes and gardens, and the identical chemicals are incorporated in consumer products such as

cleansers, shampoos and shower curtains. EPA should be required to calculate the residues of the agricultural chemical on all commodities in which it may legally occur together with pesticide residues which may occur in drinking water. The total dietary exposures, including the exposure through drinking water, should be examined by EPA in assessing risk.

In addition to an approach focusing independently on each pesticide, NRDC believes the Committee should require EPA to also consider combined risks posed by the totality of pesticides used on the same crop. In establishing or revising tolerances for any pesticide, EPA should consider the total dietary risk which results from residues of all pesticides which are legally used on the commodities. If there are four pesticides used on an apple in a single growing season, EPA should be able to assure the public not just that each pesticides' residues are safe but that eating the apple with all four kinds of residues is safe. EPA must also seek better information on possible synergisms between pesticides used in combination, which might greatly increase risk.

4. Deadlines for EPA's obligations under the statute should be set by Congress.

NRDC has found that legislation which lacks statutory deadlines for Agency action are often not implemented in a timely fashion. Often this occurs because the Agency has many other responsibilities, and the Agency assigns lower priority to those

requirements which Congress failed to assign explicit, enforceable timetables. NRDC urges the Committee to establish timetables to hasten the reduction of risk from pesticides in our food supply. Specifically, we believe that the Committee should establish an explicit timeframe for EPA's review of current tolerances or exemptions to determine whether the tolerances are adequate and whether more complete toxicity or residue chemistry data are needed.

Similarly, when data are demanded by EPA, EPA should be required by the legislation to grant no more than 4 years, the time needed for the most elaborate chronic toxicity tests, for the data submission. Ordinarily data should be submitted within a year, because in 1984 EPA required registrants to undertake the time-consuming chronic toxicity tests for most food use pesticides.

5. H.R. 4937 should require EPA to set tolerances for "inert" ingredients or metabolites of pesticides.

The federal pesticide law distinguishes between active ingredients, which kill, repel or otherwise control pests, and so-called "inert" ingredients, substances which are used to dilute, propel or stabilize the active ingredient.¹⁸ In many instances, the non-active ingredients are extremely toxic

¹⁸ The Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA), 7 U.S.C. § 136(a) and § 136(m).

chemicals.¹⁹ EPA has broadly exempted these "inert" ingredients from regulation under the FDCA. NRDC believes that current law requires EPA to set tolerances for these ingredients. However, we fear that litigation may be necessary to motivate EPA to set tolerances for these dangerous pesticide ingredients. The bill implicitly allows EPA to continue the food uses of dangerous pesticide ingredients which are pesticidally inactive. This is unnecessary and unjustifiable. Because many so-called inert ingredients are actually extremely toxic chemicals, there may be instances in which the pesticide may pose excessive risks not because of the active ingredient but instead because of the substance used to dilute, propel, or stabilize the formulation. Inert ingredients are in no way essential to the pesticide product. If a manufacturer wants to continue to use the active ingredient in or on food, the manufacturer should substitute an innocuous ingredient for the one posing a significant health threat. EPA should never allow residues of an inert ingredient to pose a health hazard.

6. H.R. 4937 should grant EPA needed "imminent hazard" authority to modify or revoke tolerances.

The current procedure for modifying or revoking tolerances is far too cumbersome to effectively protect the public when EPA

¹⁹ EPA recently listed 57 inert pesticide ingredients of toxicological concern. 52 Federal Register 13305, April 22, 1987. Included on EPA's list were extremely dangerous chemicals, some of them restricted or cancelled by EPA, such as benzene, carbon tetrachloride, chloroform, formaldehyde, and mercury oleate.

discovers a pesticide poses a substantial threat to public health. EPA Assistant Administrator Moore testified that removing a dangerous pesticide from the food supply could easily take years.²⁰ Therefore, food safety legislation should include a section authorizing EPA to issue an order to modify or revoke a tolerance when "necessary to prevent an imminent hazard to public health."

7. H.R. 4937 should require practical methods of detecting pesticide residues before a tolerance is granted.

Pesticides should not be used on food if FDA cannot readily detect the residues in food. Without the ability to detect residues, FDA cannot enforce EPA's tolerances and therefore cannot offer even the most rudimentary protection for consumers.

H.R. 4937 should require all petitions for tolerances to include a practical method for detecting residues and thereby enforcing the tolerance. The bill should establish that a method will not be considered practical unless it can be performed by the FDA on a routine basis with the personnel, equipment, and other resources available to the Agency. Establishing practical detection methods before granting food uses for pesticides is essential if FDA is to stop violative shipments from being consumed by an unsuspecting public.

²⁰ Testimony of John A. Moore, June 8, 1987, *supra*, p. 172.

III. EPA AND FDA ARE NOT IMPLEMENTING THE DELANEY CLAUSE TO PROTECT THE PUBLIC FROM CARCINOGENIC PESTICIDES IN FOODS.

The Delaney clause is widely believed to prohibit all carcinogens in food. This is a hopeful but erroneous view. The Delaney clause does not even prohibit all carcinogenic pesticides in food. Delaney applies only to a relatively narrow category of pesticides used in or on food. Even when the Delaney clause applies, the agencies charged with the implementation have routinely ignored or cleverly side-stepped the restriction.²¹

The FDCA includes two provisions which provide the authority for EPA's regulation of pesticides in food. The general safety standard of section 408²² applies to raw foods such as apples and

²¹ Congress itself created some exclusions from the application of the Delaney clause, including the 1962 DES proviso and the clause exempting substances permitted as food additives before 1958 (the "prior sanction" exception). Numerous legally questionable exceptions to the Delaney clause have also been devised by the FDA, including the "sensitivity of method" (SOM) policy, "secondary mechanism" exception, the "constituents interpretation," and FDA's recently overruled "de minimis" interpretation. See National Academy of Sciences, Board on Agriculture, Regulating Pesticides in Food: The Delaney Paradox, 1987, hereinafter NAS, pp. 37-40; Richard A. Merrill, "FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?", 5 YALE J. ON REG. 21-29, 41-49 (1988); and Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987).

²² "The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the

tomatoes, and to many processed foods, such as frozen, milled and prepared foods. Section 409, including the food additives Delaney Clause²³, applies to pesticides in those processed foods in which pesticide residues concentrate above the legal limits.

²⁴ Such concentration occurs in certain heat-processed foods such as applesauce and tomato paste.

The two FDCA pesticide standards are not consistently interpreted, nor are they consistently applied. Most commentators, including until recently both FDA and EPA, interpret the Delaney clause as a nearly categorical prohibition

consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion submitted with a certification of usefulness under subsection (1) of this section . . ." FDCA, § 408(b), 21 U.S.C. § 346(b) (1982), emphasis added.

²³ In the Federal Food, Drug and Cosmetic Act, there are actually three Delaney clauses, one for each of three categories of substances--food additives, color additives, and animal drugs--which may leave residues in food. Pesticide residues are regulated by the food additives Delaney clause, which was added to the statute in 1958. The relevant part of the food additives section reads as follows:

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary--

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal Federal Food, Drug and Cosmetic Act, § 409(c)(3), 21 U.S.C. § 348(c)(3), emphasis added.

²⁴ FDCA's definition of "food additive" excludes "pesticides on raw agricultural commodities." 21 U.S.C. § 321(s). Also exempted are processed foods "where the concentration of residue . . . is not greater than the tolerance prescribed for the raw agricultural commodity." *Id.* at § 402, 21 U.S.C. § 342(a)(2)(c).

on the use of cancer-causing substances within its scope. But FDA interprets the general safety clause as permitting the use of carcinogens on raw foods, so long as the risk they pose is not greater than 1×10^{-6} , or one cancer in a million persons exposed over a lifetime.²⁵ EPA's interpretation of its obligation under FDCA §408 to set tolerances "to the extent necessary to protect the public health" as implicitly modified by the risk-benefit standards of the FIFRA is currently on appeal in a case brought by NRDC and other public interest groups.²⁶

Only twice in the three decades since it became law has EPA invoked the Delaney clause to refuse a new food use of a carcinogenic pesticide.²⁷ Neither EPA nor FDA has cited the Delaney clause to justify banning an existing food use of a carcinogen since Congress overturned FDA's attempt to ban saccharin in 1977.²⁸

EPA does not adequately enforce the rigorous Delaney clause for the protection of the public from pesticides even in those processed food to which it unequivocally applies. Carcinogenic

²⁵ NAS SUPRA, p. 94.

²⁶ Nader v. EPA, No. 87-7103, (9th Cir., filed June 18, 1987).

²⁷ FDA invoked the Delaney clause only four times to prohibit the use of a substance in food. Merrill, SUPRA, p. 9. The National Academy of Sciences identified only two instances in which the Delaney clause was the basis of EPA's denial of tolerances for pesticides in food: fosetyl al and permethrin. NAS, SUPRA, pp. 92-93.

²⁸ Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977).

pesticides including daminozide, benomyl, dicofol, chloro-benzilate and the EBOCs²⁹ (ethylenedithiocarbamates) are known to concentrate in some processed foods, notwithstanding the Delaney prohibition.

The National Academy of Sciences reported that EPA has granted tolerances for cancer-causing pesticides on at least 31 processed foods.³⁰ NAS identified some 809 processed forms of the commodities treated with these carcinogenic pesticides.³¹ No one can be certain about the number of foods for which processing unavoidably concentrates residues of pesticide chemicals, because EPA does not have complete data revealing the effects of processing on residues. However, the large discrepancy suggests that EPA is not implementing the Delaney clause to prohibit carcinogenic pesticidal food additives.

Furthermore, the NAS also noted that the Agency has applied the Delaney clause almost exclusively to new pesticides and has virtually ignored the clause's application to pesticides registered before 1972.³² EPA's failure to enforce the Delaney clause with regard to pesticides already on the market has meant that what was intended by Congress to be a potent weapon against

²⁹ A class of fungicides, including Maneb, Mancozeb, Metiram, Nabam, and Zineb, which are extensively used in the U.S. and world wide on fruits and vegetables.

³⁰ NAS, *SHDCA*, p. 62.

³¹ NAS, *SHDCA*, p. 64.

³² NAS, *SHDCA*, pp. 40-41.

carcinogens in our diets has provided little protection from dangerous pesticides. H.R. 4937 should be amended to enhance the public's protection from carcinogenic pesticide residues in food. As drafted, the bill could be implemented to undercut the limited protection the law now demands.

IV. THE DELANEY CLAUSE IS VITAL TO THE PROTECTION OF OUR FOOD SUPPLY FROM CARCINOGENIC COLOR ADDITIVES, FOOD ADDITIVES AND ANIMAL DRUGS.

Many food industry representatives, as well as the current Food and Drug Administration, have sought to amend or repeal the three Delaney clauses in the FDCA.³³ NRDC strongly opposes any such effort. We would vehemently oppose amendments, even if coupled with improvements to the regulation of pesticides, which undermine the strict Delaney prohibition on carcinogenic food additives, animal drugs or color additives. Improved safety of the pesticides used in our food supply must not be achieved at the expense of increasing the hazards from other carcinogenic substances in food.

³³ FDA representatives recently told the House Energy and Commerce Committee: "We believe that this [negligible risk] reasoning reflects good public policy and should also apply to other substances regulated by FDA that are subject to Delaney provisions." Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, before the Health and Environment Subcommittee, House Energy and Commerce Committee, June 23, 1988, p. 4.

Thank you for the opportunity to testify on this important legislation. I look forward to working with the Committse on this and other legislation needed to enhance public health protection from pesticides in our food and in our environment.



National Food Processors Association

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STATEMENT
of the
NATIONAL FOOD PROCESSORS ASSOCIATION
before the
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE
of the
HOUSE COMMITTEE ON AGRICULTURE
on
H.R. 4937
PESTICIDE FOOD SAFETY ACT OF 1988
presented by
Lawrence T. Graham
Executive Vice President for Public Affairs
and
Jack L. Cooper
Director, Environmental Affairs
July 28, 1988

WASHINGTON, D.C. • DUBLIN, CALIF. • SEATTLE, WASH.

My name is Lawrence T. Graham. I am the Executive Vice President for Public Affairs of the National Food Processors Association. With me is Mr. Jack L. Cooper, Director, Environmental Affairs for NFPA and Mr. Clausen Ely of Covington & Burling, counsel to the Association.

We appreciate the opportunity to appear today. Please keep in mind that the views that will be expressed have not yet been thoroughly discussed with the membership. Therefore, I ask that you keep in mind the fact that we will be continuing to refine our position on the bill as we hear more comments from our membership.

Before presenting our testimony, I would like to briefly describe the National Food Processors Association (NFPA). NFPA represents some 600 companies across the country, including most of the major food processing firms. Most of our members are involved with the processing of fruits, vegetables, meats, fish, and specialty products, and other members are involved in the manufacture of processing and packaging equipment and supplies. NFPA maintains and operates three food processing research laboratories where over 100 scientific personnel conduct studies on food safety, nutrients, and innovative technologies.

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Research conducted by our laboratories and others have shown that most pesticide residues that may be present in or on raw agricultural products are removed during food processing operations, such as peeling, washing, blanching, milling and other processing operations. Thus, the vast majority of processed foods actually consumed contain residues far below the levels that may be found on raw agricultural products.

We are pleased to support the following provisions of HR 4937:

Negligible Risk Standard - When the NAS report on the "Delaney Paradox" was issued in May of last year, we testified that we supported the basic concept of negligible risk and the application of negligible risk criteria to tolerances for pesticide residues in both raw and processed foods. We stressed, however, that appropriate consideration of benefits should also be retained. We reiterate that support today and are pleased that H.R. 4937 embodies a negligible risk standard and provides for continued consideration of benefits in setting pesticide tolerances. We are also pleased that the bill provides EPA with sufficient authority to determine specific levels associated with a negligible risk based on evolving scientific data and principles.

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Consistent Regulation of Foods - We support the principle expressed in the NAS report and embodied in this bill that the regulation of pesticide residues should be consistent for both fresh and processed foods. HR 4937 would accomplish this objective by regulating all foods under Section 408 of the FD&C Act. Pesticide residues in processed foods would no longer be regulated under the Delaney provision of Section 409. Importantly, the bill provides that all processed foods for which a tolerance has not been established would have the same tolerance as established for the raw agricultural commodity, unless EPA determined that a higher tolerance was necessary and such a higher tolerance was in place.

Use of Actual Residue Data in Risk Assessments - When evaluating the relative risks of pesticide chemicals, the bill would require the use of actual pesticide use and residue data to the greatest extent possible. This is an extremely important provision. The NAS "Delaney Paradox" report is based on the erroneous assumption that all registered pesticides are used at the maximum application level and that they are present at the maximum residue level authorized by a tolerance. The use of real world pesticide use and residue data in risk assessments will result in more accurate and meaningful exposure assessments.

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While we wholeheartedly support the above aspects of the bill, we believe that additional consideration should be given to the following issues:

Need for FDA Action Levels - We recommend that the bill be amended to provide clear authority for the FDA to be able to issue action levels for pesticides that are present in the environment from past use and which unavoidably result in residues in or on raw agricultural commodities and processed foods. An example is the need for action levels for DDT that is present at detectable levels in or on some foods as a result of exposure of the food to the environment.

Need for A Statutory Requirement that EPA Tolerances and FDA Action Levels Are Uniform Across the Country - We recommend that the bill be amended to provide that all interested parties, especially state public health officials, should participate fully in the EPA pesticide tolerance setting process, but that when the EPA issues a final tolerance or the FDA issues a final action level, that those rules become uniform across the country and may not be altered by state, county, or local governments. If a state, county or local government has information that the established tolerances or action levels are not protective of public health, then they should offer that information to the EPA or FDA officials for their review and consideration.

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The decision to revise the tolerance or action level should rest only with Federal officials. The food industry needs a national system of uniform pesticide tolerances and action levels to effectively and efficiently market its products.

Evaluation of Pesticide Effectiveness and Cost - Where EPA is required to evaluate the risks of an alternative pesticide having risks greater than an existing pesticide, the Agency should also be required to assess the effectiveness and cost of the alternative as well as the actual usage and residue data.

Registration and Reregistration of Pesticides - We recommend that aspects of the bill concerning the registration and reregistration of pesticides be considered in the overall context of the reauthorization of FIFRA. The amendments to the FD&C Act proposed in HR 4937 are important and deserve consideration on their own merits.

Integrated Pest Management - The proposed IPM initiative is laudable and can be supported by the agricultural community. In fact, many NFPA members are working with their growers to implement cost effective IPM programs that result in reduced pesticide usage.

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International Marketplace - The National Food Processors

Association has a long standing policy of working to ensure equal treatment for domestic food processors operating in the international marketplace. The issue of pesticide regulation is one where there is potential for conflict between domestic and foreign laws. We support the need for vigorous enforcement of pesticide laws on both domestic and foreign producers. If US based firms are forced to comply with stricter standards than are their international competitors, they will be placed at a serious economic disadvantage. We ask that you keep this potential problem in mind as you work on this and other legislation in the pesticide area.

Summary and Conclusions - We commend the work of Congressman Roberts and this subcommittee to develop a meaningful bill to address the pesticide tolerance issues presented in the NAS report. We support the provisions of the bill which:

- * embody application of the negligible risk standard with consideration of benefits in setting pesticide tolerances;
- * provide for consistent regulation of foods under section 408 of the Act; and
- * provide for the use of actual residue data to the greatest extent possible in the evaluation of the relative risks of pesticides.

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However, we believe that the bill could be improved by providing:

- * clear authority for FDA to issue action levels for levels of pesticide residues that are unavoidably present due to their presence in the environment;
- * a statutory requirement for EPA Tolerances and FDA action levels to be uniform across the country; and
- * that pesticide registration and reregistration issues be omitted in favor of consideration in the overall context of FIFRA reauthorization.

As we stated at the outset of our statement, we will be working with our members over the coming weeks to further develop and refine our views and positions on the bill. We will keep you informed if any of our policies or positions change as a result of our continuing discussions with our members.

We appreciate this opportunity to present our comments and would be pleased to respond to any questions.

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